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CIS

# GENETIC SCREENING OF WORKERS

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# HEARING

BEFORE THE

## SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT

OF THE

## COMMITTEE ON SCIENCE AND TECHNOLOGY U.S. HOUSE OF REPRESENTATIVES

NINETY-SEVENTH CONGRESS

SECOND SESSION

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# GENETIC SCREENING OF WORKERS

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TUESDAY, JUNE 22, 1982

House of Representatives,
Committee on Science and Technology,
Subcommittee on Investigations and Oversight,
*Washington, D.C.*

The subcommittee met, pursuant to notice, at 10:05 a.m., in room 2325, Rayburn House Office Building, Hon. Albert Gore, Jr. (chairman of the subcommittee) presiding.

Present: Representatives Gore and Walker.

Staff present: David D. Clement, minority counsel.

Mr. Gore. The subcommittee will come to order. I would like to welcome our guests and witnesses this morning.

The issues conjured up by the specter of recombinant DNA techniques have always been a mixture of the miraculous and the Orwellian. Since 1976 and the Asilomar Conference, when we first began to realize not only the scientific possibilities of recombinant DNA techniques but the enormous ethical and legal considerations invoked when one develops the ability to analyze and organize the human cell, these controversies have involved the triad of Government, industry, and academia in the past, and what we will discuss here today is no exception.

Last October this subcommittee began an inquiry into the issues raised by genetic screening in occupational settings, and we closely inspected the complexity of issues associated with exclusion of fertile women from some workplaces, among other issues. As part of that inquiry, the subcommittee reviewed the scientific validity and the use of cytogenetic screening in the workplace.

What we learned was that while some of the sophisticated biochemical tests for genetic traits such as sickle cell were being developed for medical diagnosis, the development of cytogenetic screening was in its infancy. The development of valid cytogenetic tests, that is, screening tests that could by analyzing an individual's genes predict sensitivity to a particular chemical, could raise major implications in the occupational health field.

The consensus at that hearing was, however, that this technique was a science in its embryonic stages, and that we should not expect to see validated and reasonably predictive screening tests for quite a number of years. Moreover, this impression was borne out by subsequent subcommittee inquiries with the relevant Federal agencies, including the Occupational Safety and Health Administration and the National Institute of Occupational Safety and Health. Because there had been some opinion that cytogenetic screening was actually in use, however, the subcommittee determined it would be appropriate to ask the Office of Technology Assessment to undertake a comprehensive review of the entire issue.

OTA is now conducting a review of the state of the art in cytogenetic screening and the legal and ethical implications of such screening. The subcommittee, while skeptical as to whether cytogenetic screening was actually being used, asked the OTA as part of their broader study to determine by a survey if these practices were in fact being used. Much to our surprise, OTA's blind study of the Fortune 500 companies revealed that a handful of companies are currently using these methods and a more appreciable number intend to implement these practices in the next 5 years. Indeed, 16 percent indicated they intend to do so.

This is a qualitatively different impression from that which we believed as a result of last October's inquiry so, instead of putting a controversy to rest, the OTA study gives further evidence of the need to examine in much more detail the development of cytogenetic screening as well as its ramifications.

It does not require a great deal of imagination to envision the impacts of such a practice. If we learn to predict which individuals are more likely to be harmed by exposure to certain substances, it has potential to serve as a marvelous tool to protect the health of workers or as a terrible vehicle for invidious discrimination. It is precisely because of this potential and because of the obvious impact it could have on our existing statutes, which are meant to protect a worker's health as well as to eliminate job discrimination, that the Congress should be informed early on in this controversy rather than waiting until a crisis stage is reached.

I would like to thank all the witnesses for taking the time and effort to appear here today. The subcommittee appreciates your appearance.

Mr. **Gore**. I would like to call our first witnesses, the panel from the Office of Technology Assessment, Dr. Gretchen Kolsrud, accompanied by Geoffrey Karny and Dr. Ann Rose. Would the three of you make your way to the witness table, please?

Would you all remain standing and raise your right hands?

Do you solemnly swear that the testimony you are about to give will be the truth, the whole truth, and nothing but the truth, so help you God?

Ms. **Kolsrud**. I do.

Mr. **Karny**. I do.

Ms. **Rose**. I do.

Mr. **Gore**. Thank you very much.

It is always a pleasure to welcome witnesses from the Office of Technology Assessment, and particularly you, Dr. Kolsrud. I appreciate the chance to work with you and we are looking forward to the results of your longer study later in the year. We are most appreciative of this chance to look at the results of what you have found out so far.

Without objection, the entire text of your statement will be included in the record, and we will include such additional material as you provide when we review it. I would like to invite you to begin now with your presentation.

## STATEMENT OF GRETCHEN KOLSRUD, PH. D., BIOLOGICAL APPLICATIONS PROGRAM, OFFICE OF TECHNOLOGY ASSESSMENT, CONGRESS OF THE UNITED STATES, ACCOMPANIED BY GEOFFREY KARNY AND ANN ROSE

Ms. KOLSRUD. Thank you, Mr. Gore.

Mr. Gore and members of the subcommittee, I am pleased to appear here today on behalf of the Office of Technology Assessment, which I shall refer to as OTA, to discuss the preliminary findings of our survey of the use of biochemical genetic and cytogenetic testing in the workplace.

The survey is part of an OTA assessment of the subject which was undertaken at the request of the House Committee on Science and Technology and this subcommittee. Our study will be completed this fall and, as you indicated, it is a continuation of your own congressional effort which was begun last October when this subcommittee held hearings on genetic screening and the handling of high-risk groups in the workplace.

Mr. Karny, accompanying me on my right, is the director of the assessment and a lawyer specializing in genetic issues. Ann Rose is an epidemiologist and the staff person primarily responsible for the survey.

In our study we are addressing two different kinds of genetic testing. The first is biochemical genetic testing, which involves procedures that screen healthy, asymptomatic individuals for particular genetic traits. These traits may cause the individual to be at increased risk of disease when exposed to hazardous substances found in the workplace. The second kind of testing is cytogenetic testing, which involves procedures to identify damage to the chromosomes in a person's white blood cells. This damage may indicate exposure to substances causing mutation or cancer and, when found in a group of workers, may indicate that the group is at increased risk of developing cancer because of exposure to a hazardous substance.

Biochemical genetic testing, then, centers on the individual and is more likely to be used in preemployment medical examinations, while cytogenetic testing centers on a group and would be used to monitor an existing work force.

Genetic testing, according to its advocates, has the potential to play an important role in the prevention of occupational disease. By identifying workers who may be at increased risk of disease because of past or potential exposure to hazardous substances, preventive measures could be taken by the company or by the workers themselves. In addition to the direct benefits associated with improved health, there could be indirect benefits such as reduction in the cost to employers, employees, and society associated with occupational illness.

The use of this emerging technology, however, raises several questions. Are the techniques sufficiently developed to justify their use? Could they lead to job discrimination against individuals designated as "hypersusceptible" or "high-risk"? Since many of the genetic traits sought in screening are found disproportionately among some races and ethnic groups, could the use of the tests result in discrimination on the basis of race or national origin? How will their availability affect the employer's responsibility for maintaining a safe workplace? How might these procedures affect efforts to reduce the level of hazardous substances in the workplace?

Clearly, genetic testing raises many difficult and controversial issues. The concerns and controversy have been compounded by conflicting accounts on the extent of testing and the use of the results. None of the accounts examined by OTA has been based on a rigorous, scientifically valid assessment of the use of genetic testing. Therefore, in order to dispel the confusion and speculation and to provide necessary data for policy analysis, OTA surveyed major U.S. industrial companies, utilities, and unions about the use of this technology.

Now the purpose of our survey was to determine, first, the frequency of past, present, and anticipated biochemical genetic and/or cytogenetic testing in the workplace; second, which tests were used and under what circumstances; and, finally, how the results of the tests were used. The survey did not attempt to determine the number of workers that were tested. This would have required a much larger effort than the one that was conducted.

The survey was conducted for us from February 25 to June 8 of this year by the National Opinion Research Center, which I will refer to as NORC. It is a nonprofit survey research corporation affiliated with the University of Chicago. In addition to conducting the survey, NORC provided expert advice on survey design and questionnaire development. The major elements of the design--population selection, survey methodology, and questionnaire development—are discussed in greater detail in my prepared statement, and I will just summarize a few salient points here.

We chose a questionnaire by mail as the most effective means to achieve the goals of the survey. The questionnaire itself was a four-page printed instrument. It included definitions, eight questions each on the two types of testing that I defined at the beginning of my statement, a question on actions taken as a result of either type of testing, a question relating to the use of these tests in animals, a question to determine the major industrial sector in which the companies did business, and a space to elaborate on any answers.

Considerable care was taken in developing the questionnaire, a process which required approximately 2 months with several versions and extensive review. Two people on the project staff, Dr. Rose—an epidemiologist with survey experience—and Dr. Newell, a geneticist who is not present today, had primary responsibility for the instrument. NORC provided expert advice on questionnaire format and prepared the instrument. A draft was reviewed by scientists, occupational physicians, lawyers, and other experts associated with major industries and major health organizations. The reviewers were extremely helpful and we made a number of significant changes in response to their comments.

The revised version was pretested on the bottom 25 companies in the Fortune 500 list from February 25 to March 12, 1982. The response rate for the pretest was unusually high. It was 44 percent. Analysis of the results indicated that the questionnaire was reasonably clear and consistent and that it should provide the data that we sought. The project's advisory panel of experts in genetics, occupational medicine, epidemiology, law, economic, ethics, and survey design, reviewed the final draft. Minor changes were made and the final version was mailed on March 23, 1982.

Thus, confidential questionnaires were sent by NORC to the chief executive officers of the 500 largest industrial companies and 50 largest private utilities in the United States, and to the presidents of 11 major unions representing the largest number of employees in these companies; 366 organizations answered the questionnaire, which is a 65.2 percent response rate.

Our analysis of the results is preliminary at this stage. NORC's report and our findings have not been reviewed by the project's advisory panel or other experts. Nevertheless, we believe that the findings are valid and that further review will result primarily in refinements on how the findings are characterized and on how the study is presented.

Of the 366 organizations responding, six or 1.6 percent were currently using biochemical or cytogenetic tests; 17 or 4.6 percent used the tests in the past 12 years; and 59 or 16.1 percent will or may use the tests in the future. It is important to note that the questionnaire instructed respondents to include any instances of testing. Thus, positive responses can include isolated instances of testing as well as long-term testing programs.

Among the six currently testing, two are in the chemical industry, two are utilities, and two are in the electronics industry. Half of those who tested in the past are chemical companies. None of the four responding unions reported any testing.

Of the organizations that reported some biochemical genetic testing, the most frequently used test was that for sickle cell trait, for which 10 organizations tested. For each test, companies were asked about the circumstances under which the tests were done—for example, were they done routinely, were they done for research, or were they done for other reasons? Companies were also asked about the type of employee that was tested.

Respondents generally tested routinely or for other, unspecified reasons. The type of employee that was chosen for testing was most often based on ethnicity and race for sickle cell trait, and job category for the other types of tests. No organization reported basing a test on an employee's sex.

Of the organizations that reported cytogenetic testing, four tested for chromosomal aberrations and two for sister chromatid exchanges. Chromosomal aberration testing was done for unspecified reasons by three companies and sister chromatid exchange testing was done for research. Job category was the only one of the three employee-related characteristics taken into account in deciding who to test by those who answered the question.

For each of the two types of testing, we asked about the factors that were considered in decisions to implement testing and the reasons for selecting specific tests to be used. Some of the factors considered in deciding to implement testing were data from animal studies, data from epidemiologic studies, and other reasons such as protecting employees. Some of the criteria for selecting a test were its predictive value and its specificity.

Responses on the use of results of biochemical genetic or cytogenetic testing ranged from transfering an employee to changing or discontinuing a product. The most common action reported was informing an employee of a potential problem. Eight organizations reported taking such action.

In evaluating the results of our survey, the most important caveat is that despite the fairly high response rate of 65 percent, we cannot arrive at conclusive statements about the extent of testing in the population surveyed because of the low frequency of testing. The practices of 34 percent of the organizations surveyed are unknown. It is also important to remember that the questionnaire was not structured to provide information on the numbers of workers tested, as I indicated before.

In conclusion, our survey of major U.S. industrial companies, utilities, and unions has shown that genetic testing has been used by some companies but that many more are interested in using it in the future. While the percentages of positive responses cannot be generalized to the survey population or to all U.S. companies and labor unions, we at least know that 17 companies have used genetic testing the past 12 years, that 5 of the 17 and 1 other are currently testing, and that 59 organizations have expressed an interest in using these tests.

Now because of this interest and the fact that this technology continues to develop, it is appropriate to assess it and its implications. We look forward to delivering our assessment, of which this survey is only one part, to the Congress in the fall.

As this time I, Dr. Rose, and Mr. Karney would be very pleased to answer your questions or elaborate on any points.

[The prepared statement of Dr. Kolsrud follows:]

# STATEMENT OF

GRETCHEN S. KOLSRUD, Ph.D., MANAGER
BIOLOGICAL APPLICATIONS PROGRAM
OFFICE OF TECHNOLOGY ASSESSMENT
CONGRESS OF THE UNITED STATES

BEFORE THE
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE AND TECHNOLOGY
UNITED STATES HOUSE OF REPRESENTATIVES
ON
THE USE OF GENETIC TESTING IN THE WORKPLACE

JUNE 22, 1982

Mr. Chairman and Members of the Subcommittee:

I am pleased to appear here today on behalf of the Office of Technology Assessment (OTA) to discuss the preliminary findings of our survey of the use of biochemical genetic and cytogenetic testing in the workplace. The survey is part of an OTA assessment of this subject, undertaken at the request of the House Committee on Science and Technology and this Subcommittee. The assessment is a continuation of a Congressional effort begun last October, when this Subcommittee held hearings on Genetic Screening and the Handling of High-Risk Groups in the Workplace. With me are Geoffrey Karny, the director of the assessment and a lawyer specializing in genetic issues, and Ann Rose, an epidemiologist and the staff person primarily responsible for the survey.

We are addressing two different kinds of genetic testing. Biochemical genetic testing involves procedures that screen healthy, asymptomatic individuals for particular genetic traits. These traits may cause the individual to be at increased risk of disease when exposed to hazardous substances found in the workplace. Cytogenetic testing involves procedures which identify damage to the chromosomes in a person's white blood cells. This damage may indicate exposure to mutagens and/or carcinogens and, when found in a group of workers, may indicate that the group is at increased risk of developing cancer because of exposure to a hazardous substance. Biochemical genetic testing centers on the individual and is more likely to be used in pre-employment medical examinations, while cytogenetic testing centers on a group and would be used to monitor an existing workforce.

Our project, which is scheduled for completion in October, has four major goals:

1) to assess the current state of the art and expected future

developments through a review of the scientific literature and discussions with experts in the field;

2) to determine the frequency of testing in the workplace and for what purposes it was used;

3) to identify and analyze the legal, ethical, economic, and social issues raised by this technology; and

4) to discuss Congressional issues and policy options.

This technology, according to its advocates, might be able to play an important role in the prevention of occupational disease. By identifying workers who may be at increased risk of disease because of past or potential exposure to hazardous substances, additional preventive measures could be taken by the company or the workers themselves. In addition to the direct benefits associated with improved health, there could be indirect benefits, such as a reduction in the costs to employers, employees, and society associated with occupational illness. These costs include medical and insurance expenses, time lost from work, and productivity losses.

The use of this emerging technology, however, raises several concerns. Are the techniques sufficiently developed so as to predict reliably an association between either genetic damage or a person's genetic makeup and disease? Could there be job discrimination against individuals designated as "hypersusceptible" or "high-risk"? Since many of the genetic traits sought in screening are found disproportionately among some races and ethnic groups, could the use of the tests result in discrimination on the basis of race or national origin? How will the availability of the tests affect the employer's responsibility for maintaining a safe workplace? How might these procedures affect efforts to reduce the level of hazardous substances in the workplace?

Clearly, this technology raises many difficult and controversial issues. The concerns and controversy have been compounded by conflicting accounts on the extent of testing and the use of the results. None of the accounts examined by OTA has been based on a rigorous, scientifically valid assessment of the use of biochemical genetic and cytogenetic tests. Therefore, in order to dispel the confusion and speculation and to provide necessary data for policy analysis, OTA surveyed major U.S. industrial companies, utilities, and unions about their use of this technology.

## The Survey

The purpose of the survey was to determine:

1) the frequency of past, present, and anticipated biochemical genetic and/or cytogenetic testing in the workplace and whether it had been conducted on a routine, special, or research basis;
2) which tests were used and under what circumstances;
3) how the results of the tests were used; and
4) the criteria against which tests have been measured to determine acceptability for use.

The survey did not attempt to establish the magnitude of the use of these tests; that is, the number of workers affected. This information would have required a much more extensive effort.

The survey was conducted for OTA from February 25 to June 8, 1982 by the National Opinion Research Center (NORC), a nonprofit survey research corporation affiliated with the University of Chicago. In addition to conducting the survey, NORC provided expert advice on survey design and questionnaire development.

NORC sent confidential questionnaires to the chief executive officers of the 500 largest industrial companies and 50 largest private utilities in the U.S. and to the presidents of 11 major unions representing the largest number of employees in these companies. Three hundred sixty-six organizations answered the questionnaire, a 65.2% response rate, and twenty-six organizations specifically declined, a 4.6% refusal rate. Those who declined generally gave reasons of time or survey relevance to their business.

The major elements of the survey design — population selection, survey methodology, and questionnaire development — are discussed below.

## Population Selection

Although we had originally considered surveying only chemical firms, discussions with industry scientists indicated that the determining factor for testing would more likely be the company's size rather than its major product. Hazardous substances are not limited to the chemical industry, but found throughout the industrial sector and even in utilities. A company's decision to implement testing would most likely be a function of the extent and sophistication of its medical program, and sophisticated programs would most likely be found in large companies. Thus, we focused on the 500 largest U.S. companies involved in manufacturing and mining in 1980 and the 50 largest private U.S. utilities in 1980, as identified by Fortune magazine. Since unions are also interested in the health of their members, we chose the eleven major ones representing employees in these industries, as identified by the Department of Labor's Directory of National Unions and Employee Associations (1979). We surveyed the entire population rather than just a sample in order to eliminate sampling error that might result from a small number of companies testing and to avoid other potential problems associated with sample selection.

## Survey Methodology

We chose a questionnaire sent by mail as the most effective means to achieve the goals of the survey. It was the most feasible, cost-effective way to gather the needed information and to assure confidentiality.

Protecting confidentiality of the individual responses was viewed as crucial for securing both a high rate of participation and accurate information, particularly in view of the sensitive nature of the subject. No identifying marks were placed on the questionnaire, and respondents were urged not to do so on their own. Results can only be compiled in aggregate form. Follow-up procedures were possible because respondents were asked to return separately an enclosed postcard to NORC, which named their organization and stated that the questionnaire had been completed.

The questionnaire was pretested on the bottom 25 companies in the Fortune 500 from February 25 to March 12, 1982. Forty-four percent of the sample responded. After analysis of the results, minor format changes were made, and two questions were deleted. The remainder of the population was surveyed from March 23 to June 8, 1982.

The questionnaires were sent to the chief executives officers and presidents with the suggestion that they route it to the person responsible for health and safety matters. This was done in an attempt to demonstrate the importance of the survey and to assure that it got quickly to the appropriate person in the organization, thereby increasing the chances of a timely response.

Questionnaires were accompanied by two one-page letters -- one from the Office of Technology Assessment, signed by John Gibbons, the Director, and one from NORC, signed by Cynthia Thomas, NORC's project director -- and by a post card and a return envelope. A list of the names of the members of the project's advisory panel was also enclosed. (Copies of the questionnaire, letters, and advisory panel membership list are attached.)

NORC commenced follow-up procedures on April 19th by sending ninety-eight letters to nonrespondents. A second effort involved telephone calls to 200 of the nonrespondents. The effort concentrated on the Fortune 100 companies and those in key industry groups, such as chemicals, rubber and plastic products, metal manufacturing, and pharmaceuticals. Ultimately, 366 questionnaires were returned or the information required to complete them was obtained by telephone or letter, yielding a response rate of 65.2%. Twenty-six organizations (4.6%) specifically declined to complete the questionnaire, generally citing reasons of time or survey relevance.

## Questionnaire Development

The questionnaire was a four page printed instrument. Two slightly different versions were used, depending on whether it was sent to a company or a union; however, the differences are of semantic nature. (See attached copies.) It was composed of the following parts:

1) Introductory paragraphs, which gave instructions and defined terminology;
2) Eight questions on biochemical genetic testing and eight on cytogenetic testing;
3) A question on actions taken as a result of either type of testing;
4) A question relating to the use of these tests in animals;
5) A question to determine the major industrial sector in which the companies did business; and
6) A space for explaining the answer to any question or adding additional information.

Providing the opportunity to explain an answer or add information is critical for increasing response rate and providing more precise data. This was suggested by our industrial reviewers and is supported by survey methodology literature.

The questionnaire reflected two assumptions made by the staff. First, we assumed that an individual within the organizations being surveyed would be familiar with this subject. We believe this assumption to be appropriate because the subject has been widely discussed by various professional groups concerned with occupational health, including committees within major industrial trade associations. Second, we assumed that our definitions of biochemical genetic testing and cytogenetic testing would be carefully and consistently followed in answering the questionnaire. Since different experts use the terminology in slightly different ways, we defined these terms in the first paragraph of the questionnaire. We have no reason to believe these assumptions were not valid.

The questionnaire was developed over a period of approximately two months, during which it went through several versions and extensive review. Two people on the project staff, an epidemiologist with survey experience and a geneticist, had primary responsibility for the instrument. NORC provided expert advice on questionnaire format and prepared the instrument. A draft was reviewed by scientists, occupational physicians, lawyers, and other experts associated with the following organizations: E. I. Du Pont de Nemours, Shell Oil Company, American Industrial Health Council, Chemical Manufacturers Association, American Occupational Medical Association, American Academy of Occupational Medicine, and the Genetic Toxicology Association. In view of time constraints, these people gave their opinions as individuals rather than as representing a position of their organization. The reviewers were extremely helpful, and we made significant changes in response to their comments.

This revised version was the one used in the pretest. The response rate for the pretest (44%) was considered unusually high. Analysis of the results indicated that the questionnaire was reasonably clear and consistent and that it should provide the data sought. Some changes were made to further enhance clarity. Because the changes were relatively minor, pretest responses were included in the final analysis.

The project's advisory panel of experts in genetics, occupational medicine, epidemiology, law, economics, ethics, and survey design reviewed the final draft. They suggested certain changes in the instructions to further clarify the type of testing for which information was sought and the deletion of two questions. These changes were made, and the questionnaires were mailed on March 23, 1982.

## Results

Our analysis of the results is preliminary at this stage. NORC's report and our findings have not been reviewed by the project's advisory panel or other experts. Nevertheless, we believe that the findings are valid and that further review will result primarily in refinements on how the findings are characterized and how the study is presented.

### Overall Rates of Testing

Of the 366 (65.2%) organizations responding, 6 (1.6%) were currently using biochemical or cytogenetic tests, 17 (4.6%) used the tests in the past 12 years, and 59 (16.1%) will or may use the tests in the future. Of those organizations that have tested in the past 12 years, five are currently using these tests. One organization reported current testing but none in the past 12 years. It is important to note that the questionnaire instructed respondents to include any instances of testing; thus, positive responses can include isolated instances of testing as well as long-term testing programs. Among the six currently testing, two are in the chemical industry, two are utilities, and two are in the electronics industry. Half of those who tested in the past are chemical companies. None of the four responding unions reported any testing. These results are set forth in more detail in Tables I-III.

## Types of Testing: Biochemical Genetic and Cytogenetic

Organizations that reported some biochemical genetic testing were asked whether they had ever tested employees for genetic traits associated with: (A) any red blood cell and serum disorders, (B) liver detoxification systems, (C) immune system markers, or (D) heterozygous chromosomal instabilities. Within each of the four broad categories A through D, several examples were included. Of those who have ever tested, there were fourteen organizations that tested in category A, three in category B, five in category C and none in category D. Those organizations that have used tests in category A frequently used more than one type of test. The most frequently used test was that for sickle cell trait, for which ten organizations have tested. The G-6-PD deficiency test was the second most frequently used. (See Table IV for summary of the frequency of individual biochemical genetic tests.)

For each test, companies were asked about the circumstances under which the tests were done (i.e., routinely, for research, or for other reasons) and the type of employee tested. Respondents generally tested routinely or for other unspecified reasons. (See Table IV.) The type of employee chosen for testing was most often based on ethnicity and race for sickle cell trait testing, and job category for other types of tests. No organization reported basing a test on an employee's sex. (See Table V.)

Organizations that reported cytogenetic testing were asked if they had looked for chromosomal aberrations, sister chromatid exchanges (SCEs), mutations by assaying DNA, mutations by assaying enzymes, or something else. Four organizations have tested for chromosomal aberrations and two for SCEs. None claimed to have tested for mutations by assaying either DNA or enzymes. Chromosomal aberration testing was done for unspecified reasons by three companies; SCE testing was done for research purposes. (See Table IV.) Job category was the only one of the three employee-related characteristics taken into account in deciding who to test by those who answered the question. (See Table V.)

For each of the two main types of testing (biochemical genetic and cytogenetic), several questions were asked about factors considered in decisions to implement testing and criteria employed in selecting specific tests. All categories provided received at least one response. For example, some of the factors involved in decisions to implement testing were data from animal studies, data from epidemiologic studies, and other reasons such as protecting employees. (See Table VI). Some of the criteria for selecting a particular test were its predictive value and specificity. (See Table VII.)

## Results of Testing

Organizations who responded to the way they used the results of biochemical genetic or cytogenetic testing ranged from transferring an employee to changing or discontinuing a product. The most common action reported was informing an employee of a potential problem. Eight organizations reported taking such action. The actions taken are listed in Table VIII.

## Caveats

In evaluating the results of our survey, several caveats must be considered. First, we have no knowledge about the level of effort employed in completing each questionnaire. This could be a problem with holding companies, which have autonomously operating subsidiaries. Second, a limitation of an anonymous questionnaire is that one cannot contact a respondent about missing information or unclear responses. For this survey, approximately 3% of the respondents failed to answer each item in questions 1-6. Eight questionnaires did not contain enough information to allow the respondent to be classified as one of the Fortune 500 companies or as a utility. Third, the use of postcards for follow-up has pitfalls. Respondents may return postcards but not questionnaires or vice versa; NORC received 293 post cards and 366 questionnaires. Fourth, despite the fairly high response rate (65%), we cannot arrive at conclusive statements about the extent of testing in the population surveyed because of the low frequency of testing. The practices of 34% of the organizations surveyed are unknown. Fifth, the questionnaire was not structured to provide information on the numbers of workers tested.

## Conclusions

Our survey of major U.S. industrial companies, utilities, and unions has shown that genetic testing has been used by some companies but that many more are interested in using it in the future. While the percentages of positive responses cannot be generalized to the survey population or to all U.S. companies and labor unions, we at least know that: 1) 17 companies have used genetic testing in the past twelve years; 2) five of the 17 and one other are currently testing; and 3) 59 organizations have expressed an interest in using these tests. Because of this interest and the fact that this technology continues to develop, it is appropriate to assess the technology and its implications. We look forward to delivering our assessment to the Congress this fall.

At this time, I would be happy to answer any questions.

## Table I

### Distribution of Current, Past, Future Biochemical Genetic and/or Cytogenetic Testing By Type of Organization (Based on 366 Responses)

| Organization Type | Testing | | |
|---|---|---|---|
| | Current | Past | Future |
| Manufacturing/Mining Companies | 4 | 16 | 49 |
| Private Utility Companies | 2 | 1 | 9 |
| Unions | 0 | 0 | 0 |
| Other | 0 | 0 | 1 |
| Total | 6<br>(6/366=1.6%) | 17<br>(17/366=4.6%) | 59<br>(59/366=16.1%) |

## Table II

### Frequency of Current, Past, Future Genetic Testing By Type of Testing (Based on 366 Responses)

| | Testing | | |
|---|---|---|---|
| Type | Current | Past | Future |
| Biochemical Genetic | 5(1.4%) | 12(3.3%) | 54(14.8%) |
| Cytogenetic | 2(0.5%) | 6(1.6%) | 52(14.2%) |

## Table III

### Distribution of Current, Past, Future Biochemical Genetic and/or Cytogenetic Testing By Main Industrial Classification[a] of Corporation (Based on 366 Responses)

| Main Industrial Classification | Testing | | |
|---|---|---|---|
| | Current | Past | Future |
| Chemical | 2 | 8 | 11 |
| Utilities | 2 | 1 | 10 |
| Petroleum | 0 | 0 | 4 |
| Pharmaceuticals | 0 | 0 | 3 |
| Rubbers/Plastics | 0 | 0 | 3 |
| Metals | 0 | 0 | 2 |
| Others | 2[b] | 8 | 26 |
| Total | 6<br>(6/366=1.6%) | 17<br>(17/366=4.6%) | 59<br>(59/366=16.1%) |

[a] Main industrial classification based on the first listed response of respondent to question concerning the major industrial classification of their company.

[b] Both of these companies report electronics as their main industrial classification.

## Table IV

### Purpose for Conducting
### Biochemical Genetic and Cytogenetic Testing
### Distribution by Specific Test

| Purpose | Biochemical Genetic | | | | | | | Cytogenetic | |
|---|---|---|---|---|---|---|---|---|---|
| | Sickle Cell | G-6-PD | SAT | Methemoglobin Reductase | Unspecified Red Blood Cell/ Serum Disorder | Unspecified Liver Detox | Unspecified Immune System Markers | Chromosomal Aberrations | Sister Chromatid Exchanges |
| Routine | 5 | 3 | 1 | 0 | 1 | 1 | 4 | 1 | 0 |
| Research | 1 | 0 | 2 | 1 | 2 | 1 | 0 | 1 | 2 |
| Other | 6 | 2 | 2 | 1 | 2 | 1 | 3 | 3 | 0 |
| Total No. Respondents Utilizing Test[a] | 10 | 4 | 4 | 1 | 3 | 2 | 4 | 4 | 2 |

[a] Since categories above are not mutually exclusive, total can be less than/more than sum of categories

## Table V

Criteria for Biochemical Genetic and Cytogenetic Testing:
Distribution by Specific Test

| Criteria | Biochemical Genetic | | | | | | | Cytogenetic | |
|---|---|---|---|---|---|---|---|---|---|
| | Sickle Cell | G-6-PD | SAT | Methemoglobin Reductase | Unspecified Red Blood Cell/ Serum Disorder | Unspecified Liver Detox | Unspecified Immune System Markers | Chromosomal Aberrations | Sister Chromatid Exchange |
| Job Category | 1 | 2 | 2 | 0 | 2 | 1 | 1 | 2 | 1 |
| Ethnicity/Race | 7 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Sex | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Total No. Respondents Utilizing Test[a] | 10 | 4 | 4 | 1 | 3 | 2 | 4 | 4 | 2 |

[a] Since categories above are not mutually exclusive, total can be less than/more than sum of categories

## Table VI
## Distribution of Factors Involved in Decision To Implement Biochemical Genetic or Cytogenetic Testing

| Factors | Type Testing | |
|---|---|---|
| | Biochemical Genetic | Cytogenetic |
| Data Epidemiologic Studies | 6 | 2 |
| Data Animal Studies | 4 | 2 |
| Legal Consequencies of Not Testing | 3 | 0 |
| Union/Employee Initiative | 3 | 0 |
| Cost-Benefit Analysis | 2 | 0 |
| Other[a] | 4 | 3 |

[a] includes reasons related to protecting employees, research findings

## Table VII

### Distribution of
### Criteria for Test Selection
### Of Biochemical Genetic or Cytogenetic Testing

| Criteria[*] | Type Testing | |
|---|---|---|
| | Biochemical Genetic | Cytogenetic |
| Predictive Value of Test[a] | 5 | 1 |
| Specificity of Test[b] | 5 | 1 |
| Scientific Concensus | 4 | 2 |
| Sensitivity of Test[c] | 3 | 0 |
| Cost of Test | 2 | 0 |
| Other[d] | 4 | 3 |

[*] a respondent may have based their selection for a test on one or more of the above criteria.

[a] predictive value of test is the likelihood that the disease status of the individual will be correctly identified by the test, i.e. disease free individual will have negative test result, disease individual will have positive test result.

[b] specificity of test: ability of test to correctly identify individuals without disease

[c] sensitivity of test: ability of test to correctly identify individuals with disease

[d] includes research findings (general)

## Table VIII

### Distribution of
### Actions Taken By Respondents
### After Biochemical Genetic or Cytogenetic Testing

| Type Action* | Number of Companies |
|---|---|
| Informed Employee | 8 |
| Transferred Employee | 5 |
| Personal Protection Devices | 3 |
| Other Action | 3 |
| Suggested Employee Seek Other Job | 2 |
| Installed Engineering Control | 2 |
| Implemented Research Program | 1 |
| Discontinued/Changed Product | 1 |

* a respondent may have taken more than one action.

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JOHN H. GIBBONS

Congress of the United States
OFFICE OF TECHNOLOGY ASSESSMENT
WASHINGTON, D.C. 20510

JOHN H. GIBBONS
[illegible]

March 22, 1982

Dear Mr.

The Committee on Science and Technology of the U.S. House of Representatives has requested this office to carry out a comprehensive study of the policy issues arising from potential occupational genetic testing. The Committee expects the study to provide the Congress with full and fair information on a complex and sensitive topic. A crucial component of our study will be information and advice from leading U.S. corporations. Since your company is a world leader in many areas relevant to the study, we believe it is extremely important for us to benefit from any experience you may have with such testing programs.

The Office of Technology Assessment (OTA) is a nonpartisan congressional agency that assists the Congress in dealing with complex technical issues. OTA is governed by a bipartisan Congressional board composed of six Representatives and six Senators. A council of ten members eminent in science, technology, and education serves in an advisory capacity. This study is also being assisted by an advisory panel of experts in genetics, occupational medicine, law, and policy from industry, labor, and academia. A list of advisory panel members and their affiliations is enclosed.

We have asked the National Opinion Research Center of the University of Chicago (NORC) to assist OTA by collecting and processing data via a questionnaire. The data will be presented to OTA in aggregate form only, and the raw data will be destroyed.

NORC's brief questionnaire is attached. We believe it will be most helpful if you direct it to your chief executive for health affairs. We respectfully request a response to the questionnaire as soon as possible and are prepared to share the results of the analysis with you when it is completed.

If you have any questions about the study or about OTA, please feel free to contact me at (202) 224-3695, or Geoffrey M. Karny, OTA project director, at (202) 226-2090. Cynthia Thomas, NORC project director, can be contacted about the survey at (212) 971-8200.

Sincerely,

Jack Gibbons

John H. Gibbons

NORC
National Opinion Research Center
University of Chicago
461 Eighth Avenue New York, N.Y. 10001 212/971-8200

March 23, 1982

As one of the leading corporations in this country, your organization has been selected to participate in an important survey we are conducting for the Office of Technology Assessment (OTA) of the United States Congress on the state-of-the-art of genetic and cytogenetic testing programs. The enclosed letter from the OTA describes this study in more detail.

The National Opinion Research Center (NORC) is a not-for-profit academic research corporation affiliated with the University of Chicago. The oldest survey research facility established to do social research in the public interest, NORC has conducted over a thousand studies since its founding in 1941, and has developed careful and systematic methods for ensuring confidentiality. Names are never associated with responses to questions, and data collected are used only for statistical purposes.

It is very important that you complete the enclosed brief questionnaire as soon as possible. Your answers to the questions should include any instance of testing in your corporation, or in any of your subsidiary companies.

To ensure confidentiality, the questionnaire carries no identifying information. Please mail the completed questionnaire in the prepaid NORC envelope. Then, complete and mail the enclosed prepaid post-card. This will inform us that you have participated in the survey by completing a questionnaire.

If you have any questions about the questionnaire, please feel free to telephone me at (212) 971-8200.

Thank you very much.

Sincerely yours,

Cynthia Thomas

Cynthia Thomas
Project Director

NORC/4354 3/82

## WORKPLACE SURVEY

## INSTRUCTIONS FOR COMPLETING THE QUESTIONNAIRE

The questions concern biochemical genetic and/or cytogenetic testing that may have been conducted by your company on one or more employees or potential employees. By conduct we mean do, contract for, or arrange for. By biochemical genetic tests we mean tests which screen healthy, asymptomatic individuals for the particular genetic traits listed in question 7, and not standard blood chemistry tests or tests used solely for diagnosis. Cytogenetic tests are intended to detect chromosomal aberrations or sister chromatid exchanges.

Do not sign the questionnaire or record any identifying information on it. Answers should include any instances of testing in your corporation.

Please return the questionnaire to NORC before April 12.

---

1. Is your company currently conducting biochemical genetic testing of employees or potential employees? Yes ☐ No ☐

2. Has your company conducted any biochemical genetic testing of employees or potential employees in the past twelve years? Yes ☐ No ☐

3. Does your company anticipate conducting biochemical genetic testing in the next five years? Yes ☐ No ☐ Possibly ☐

4. Is your company currently conducting cytogenetic testing of employees or potential employees? Yes ☐ No ☐

5. Has your company conducted any cytogenetic testing of employees or potential employees in the past twelve years? Yes ☐ No ☐

6. Does your company anticipate conducting cytogenetic testing during the next five years? Yes ☐ No ☐ Possibly ☐

---

IF YOUR COMPANY NEVER HAS DONE EITHER BIOCHEMICAL GENETIC OR CYTOGENETIC TESTING, SKIP TO QUESTION 18.

IF BIOCHEMICAL GENETIC TESTING HAS EVER BEEN DONE, PLEASE ANSWER QUESTIONS 7-11. IF NOT, PLEASE SKIP TO Q. 12.

| | Yes | No |
|---|---|---|
| 7. Has your company tested workers for . . . | | |
| A. any red blood cell and serum disorders, including sickle cell trait, glucose-6-phosphate dehydrogenase deficiency (G-6-PD), methemoglobin reductase deficiency, serum alpha-1-antitrypsin deficiency (SAT), alpha and beta thalassemias? | ☐ | ☐ |
| B. any liver detoxification systems, including aryl hydrocarbon hydroxylase inducibility (AHH), slow vs fast acetylation? | ☐ | ☐ |
| C. any immune system markers, including allergic respiratory disease, contact dermatitis, histocompatibility markers (HLA)? | ☐ | ☐ |
| D. any heterozygous chromosomal instabilities, including Bloom syndrome, Fanconi syndrome, ataxia-telangiectasia, xeroderma pigmentosum? | ☐ | ☐ |

ENTER BELOW NAME OF EACH SPECIFIC CONDITION TESTED FOR (e.g., G-6-PD). ANSWER QUESTIONS 8 & 9 FOR EACH. IF MORE THAN 4 CONDITIONS, RECORD ON ADDITIONAL SHEET OF PAPER.

| ENTER SPECIFIC CONDITION NAME HERE——> | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Yes | No | Yes | No | Yes | No | Yes | No |
| 8. Was testing done . . .<br>a) routinely (e.g., yearly) or during regular specified circumstances? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| b) for research purposes (e.g., hypothesis testing)? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| c) for any other reasons? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| 9. Was testing to detect increased risk of disease ever based on an employee's . . .<br>a) job category? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| b) sex? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| c) ethnic or racial background? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

10. What factors have been considered in decisions to implement any biochemical genetic testing programs?

A. Cost benefit analysis ☐
B. Data suggesting a possible association between chemical exposure and illness in animal studies ☐
C. Data suggesting a possible association between chemical exposure and illness in epidemiologic studies ☐
D. Legal consequences of failure to test ☐
E. Union/employee initiative ☐
F. Something else. What? ________________ ☐

11. What criteria were employed in the choice of a specific test?

A. Predictive value of the test ☐
B. Sensitivity of the test ☐
C. Specificity of the test ☐
D. Scientific consensus ☐
E. Cost of the test ☐
F. Something else. What? ☐

IF CYTOGENETIC TESTING HAS EVER BEEN DONE, PLEASE ANSWER QUESTIONS 12-16. IF NOT, PLEASE SKIP TO Q. 18.

12. Has your company tested workers for exposure to chemicals by looking for . . .

| | Yes | No |
|---|---|---|
| A. chromosomal aberrations | ☐ | ☐ |
| B. sister chromatid exchanges (SCE) | ☐ | ☐ |
| C. mutations by assaying the DNA | ☐ | ☐ |
| D. mutations by assaying the enzymes | ☐ | ☐ |
| E. something else? What? ______________ | ☐ | ☐ |

ENTER BELOW NAME OF EACH SPECIFIC CONDITION TESTED FOR (e.g., SCE). ANSWER QUESTIONS 13 & 14 FOR EACH. IF MORE THAN CONDITIONS, RECORD ON ADDITIONAL SHEET OF PAPER.

| ENTER SPECIFIC CONDITION NAME HERE ——> | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Yes | No | Yes | No | Yes | No | Yes | No |
| 13. Was testing done . . .<br>a) routinely (e.g., yearly) or during regular specified circumstances? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| b) for research purposes (e.g., hypothesis testing)? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| c) for any other reasons? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| 14. Was testing to detect increased risk of disease ever based on an employee's. . .<br>a) job category? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| b) sex? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| c) ethnic or racial background? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

15. What factors have been considered in decisions to implement any cytogenetic testing programs?

A. Cost benefit analysis ☐
B. Data suggesting a possible association between chemical exposure and illness in animal studies ☐
C. Data suggesting a possible association between chemical exposure and illness in epidemiologic studies ☐
D. Legal consequences of failure to test ☐
E. Union/employee initiative ☐
F. Something else. What? ______________ ☐

16. What criteria were employed in the choice of a specific test?

A. Predictive value of the test ☐
B. Sensitivity of the test ☐
C. Specificity of the test ☐
D. Scientific consensus ☐
E. Cost of the test ☐
F. Something else. What? ☐ ______________

17. Which actions has your company ever taken as a result of biochemical genetic or cytogenetic testing?

A. Informed employee of a potential problem ☐

B. Suggested employee seek job elsewhere ☐

C. Placed an employee or transferred an employee to a different job in the company ☐

D. Implemented engineering controls ☐

E. Recommended personal protection devices ☐

F. Implemented a research program ☐

G. Discontinued a product or changed materials in a product ☐

H. Some other action. What? ☐

____________________________

---

| 18. Has your company ever conducted any testing on whole animals or their cultured cells for . . . | Yes | No |
|---|---|---|
| A. chromosomal aberrations or sister chromatid exchanges as a result of exposure to workplace chemicals? | ☐ | ☐ |
| B. genetic predisposition to harmful effects from exposure to workplace chemicals? | ☐ | ☐ |

---

19. What is the major industrial classification of your company (such as chemicals, food or textiles)?

---

20. Please use this space for your comments, if any, about these questions.

---

Thank you for completing this questionnaire. The information you have provided will be held in strict confidence. Data will be made available to Congress in statistical form only.

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JOHN H. GIBBONS

Congress of the United States
OFFICE OF TECHNOLOGY ASSESSMENT
WASHINGTON, D.C. 20510

JOHN H. GIBBONS
DIRECTOR

March 22, 1982

Dear Mr.

The Committee on Science and Technology of the U.S. House of Representatives has requested this office to carry out a comprehensive study of the policy issues arising from potential occupational genetic testing. The Committee expects the study to provide the Congress with full and fair information on a complex and sensitive topic. A crucial component of our study will be information and advice from leading U.S. labor organizations. Since your union is a world leader in many areas relevant to the study, we believe it is extremely important for us to benefit from any experience you may have with such testing programs.

The Office of Technology Assessment (OTA) is a nonpartisan congressional agency that assists the Congress in dealing with complex technical issues. OTA is governed by a bipartisan Congressional board composed of six Representatives and six Senators. A council of ten members eminent in science, technology, and education serves in an advisory capacity. This study is also being assisted by an advisory panel of experts in genetics, occupational medicine, law, and policy from industry, labor, and academia. A list of advisory panel members and their affiliations is enclosed.

We have asked the National Opinion Research Center of the University of Chicago (NORC) to assist OTA by collecting and processing data via a questionnaire. The data will be presented to OTA in aggregate form only, and the raw data will be destroyed.

NORC's brief questionnaire is attached. We believe it will be most helpful if you direct it to your director for health and safety. We respectfully request a response to the questionnaire as soon as possible and are prepared to share the results of the analysis with you when it is completed.

If you have any questions about the study or about OTA, please feel free to contact me at (202) 224-3695, or Geoffrey M. Karny, OTA project director, at (202) 226-2090. Cynthia Thomas, NORC project director, can be contacted about the survey at (212) 971-8200.

Sincerely,

John H. Gibbons

John H. Gibbons

NORC
National Opinion Research Center
University of Chicago
461 Eighth Avenue New York, N.Y. 10001 212/971-8200

March 23, 1982

Dear

As one of the leading unions in this country, you have been selected to participate in an important survey we are conducting for the Office of Technology Assessment (OTA) of the United States Congress on the state-of-the-art of genetic and cytogenetic testing programs. The enclosed letter from the OTA describes this study in more detail.

The National Opinion Research Center (NORC) is a not-for-profit academic research corporation affiliated with the University of Chicago. The oldest survey research facility established to do social research in the public interest, NORC has conducted over a thousand studies since its founding in 1941, and has developed careful and systematic methods for ensuring confidentiality. Names are never associated with responses to questions, and data collected are used only for statistical purposes.

It is very important that you complete the enclosed brief questionnaire as soon as possible. Your answers to the questions should include any instance of testing in your union.

To ensure confidentiality, the questionnaire carries no identifying information. Please mail the completed questionnaire in the prepaid NORC envelope. Then, complete and mail the enclosed prepaid post-card. This will inform us that you have participated in the survey by completing a questionnaire.

If you have any questions about the questionnaire, please feel free to telephone me at (212) 971-8200.

Thank you very much.

Sincerely yours,

Cynthia Thomas
Project Director

NORC/4354 3/82

## WORKPLACE SURVEY

### INSTRUCTIONS FOR COMPLETING THE QUESTIONNAIRE

The questions concern biochemical genetic and/or cytogenetic testing that may have been conducted by your union on one or more union members or potential members. By conduct we mean do, contract for, or arrange for. By biochemical genetic tests we mean tests which screen healthy, asymptomatic individuals for the particular genetic traits listed in question 7, and not standard blood chemistry tests or tests used solely for diagnosis. Cytogenetic tests detect chromosomal aberrations or sister chromatid exchanges.

Do not sign the questionnaire or record any identifying information on it. Answers should include any instances of testing in your union.

Please return the questionnaire to NORC before April 12.

---

1. Is your union currently conducting biochemical genetic testing of members or potential members? Yes ☐ No ☐

2. Has your union conducted any biochemical genetic testing of members or potential members in the past twelve years? Yes ☐ No ☐

3. Does your union anticipate conducting biochemical genetic testing in the next five years? Yes ☐ No ☐ Possibly ☐

4. Is your union currently conducting cytogenetic testing of members or potential members? Yes ☐ No ☐

5. Has your union conducted any cytogenetic testing of members or potential members in the past twelve years? Yes ☐ No ☐

6. Does your union anticipate conducting cytogenetic testing during the next five years? Yes ☐ No ☐ Possibly ☐

---

IF YOUR UNION NEVER HAS DONE EITHER BIOCHEMICAL GENETIC OR CYTOGENETIC TESTING, SKIP TO QUESTION 18.

[illegible] IF NOT, PLEASE SKIP TO Q. 11.

| | Yes | No |
|---|---|---|
| 7. Has your union tested members for . . . | | |
| A. any red blood cell and serum disorders, including sickle cell trait, glucose-6-phosphate dehydrogenase deficiency (G-6-PD), methemoglobin reductase deficiency, serum alpha-1-antitrypsin deficiency (SAT), alpha and beta thalassemias? | ☐ | ☐ |
| B. any liver detoxification systems, including aryl hydrocarbon hydroxylase inducibility (AHH), slow vs fast acetylation? | ☐ | ☐ |
| C. any immune system markers including allergic respiratory disease, contact dermatitis, histocompatibility markers (HLA)? | ☐ | ☐ |
| D. any heterozygous chromosomal instabilities including Bloom syndrome, Fanconi syndrome, ataxia-telangiectasia, xeroderma pigmentosum? | ☐ | ☐ |

---

ENTER BELOW NAME OF EACH SPECIFIC CONDITION TESTED FOR (e.g., G-6-PD). ANSWER QUESTIONS # 8 & 9 FOR EACH. IF MORE THAN 4 CONDITIONS, RECORD ON ADDITIONAL SHEET OF PAPER.

| ENTER SPECIFIC CONDITION NAME HERE——> | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Yes | No | Yes | No | Yes | No | Yes | No |
| 8. Was testing done . . . | | | | | | | | |
| a) routinely (e.g., yearly) or during regular specified circumstances? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| b) for research purposes (e.g., hypothesis testing)? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| c) for any other reasons? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| 9. Was testing to detect increased risk of disease ever based on a member's . . . a) job category? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| b) sex? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| c) ethnic or racial background? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

10. What factors have been considered in decisions to implement any biochemical genetic testing programs?

- A. Cost benefit analysis ☐
- B. Data suggesting a possible association between chemical exposure and illness in animal studies ☐
- C. Data suggesting a possible association between chemical exposure and illness in epidemiologic studies ☐
- D. Legal consequences of failure to test ☐
- E. Union member initiative ☐
- F. Something else. What? ______________ ☐

---

11. What criteria were employed in the choice of a specific test?

| | | | |
|---|---|---|---|
| A. Predictive value of the test | ☐ | D. Scientific consensus | ☐ |
| B. Sensitivity of the test | ☐ | E. Cost of the test | ☐ |
| C. Specificity of the test | ☐ | F. Something else. What? ______________ | ☐ |

[illegible] ever been done, PLEASE ANSWER QUESTIONS 12-16. IF NOT, PLEASE SKIP TO Q. 18.

12. Has your union tested members for exposure to chemicals by looking for . . .

| | Yes | No |
|---|---|---|
| A. chromosomal aberrations | ☐ | ☐ |
| B. sister chromatid exchanges (SCE) | ☐ | ☐ |
| C. mutations by assaying the DNA | ☐ | ☐ |
| D. mutations by assaying the enzymes | ☐ | ☐ |
| E. something else? What? ______________ | ☐ | ☐ |

ENTER BELOW NAME OF EACH SPECIFIC CONDITION TESTED FOR (e.g., SCE). ANSWER QUESTIONS 13 & 14 FOR EACH. IF MORE THAN 4 CONDITIONS, RECORD ON ADDITIONAL SHEET OF PAPER.

| ENTER SPECIFIC CONDITION NAME HERE——> | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Yes | No | Yes | No | Yes | No | Yes | No |
| 13. Was testing done . . .<br>a) routinely (e.g., yearly) or during regular specified circumstances? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| b) for research purposes (e.g., hypothesis testing)? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| c) for any other reasons? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| 14. Was testing to detect increased risk of disease ever based on a member's . . .<br>a) job category? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| b) sex? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| c) ethnic or racial background? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

15. What factors have been considered in decisions to implement any cytogenetic testing programs?

A. Cost benefit analysis ☐
B. Data suggesting a possible association between chemical exposure and illness in animal studies ☐
C. Data suggesting a possible association between chemical exposure and illness in epidemiologic studies ☐
D. Legal consequences of failure to test ☐
E. Union member initiative ☐
F. Something else. What? ______________ ☐

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16. What criteria were employed in the choice of a specific test?

A. Predictive value of the test ☐
B. Sensitivity of the test ☐
C. Specificity of the test ☐
D. Scientific consensus ☐
E. Cost of the test ☐
F. Something else. What? ☐
______________

Which actions has your union ever taken as a result of biochemical genetic or cytogenetic testing?

Informed member of a potential problem ☐

Suggested member seek job elsewhere ☐

Suggested member seek transfer to a different job in the corporation ☐

Recommended corporation implement engineering controls ☐

Recommended corporation provide personal protection devices ☐

F. Recommended corporation implement a research program ☐

G. Recommended corporation discontinue a product or change materials in a product ☐

H. Implemented our own research program ☐

I. Negotiated items C,D, E or F in a health/safety contract ☐

J. Some other action. What? ☐

____________________________________

---

| Has your union ever conducted any testing on whole animals or their cultured cells for . . . | Yes | No |
|---|---|---|
| chromosomal aberrations or sister chromatid exchanges as a result of exposure to workplace chemicals? | ☐ | ☐ |
| genetic predisposition to harmful effects from exposure to workplace chemicals? | ☐ | ☐ |

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What are the major industrial classifications (such as chemical, food, or textiles) of those companies in the Fortune 500 in which your members work?

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Please use this space for your comments, if any, about these questions.

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ank you for completing this questionnaire. The information you have provided will be held in rict confidence. Data will be made available to Congress in statistical form only.

## OCCUPATIONAL GENETIC TESTING ADVISORY PANEL

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Mr. **Gore**. Thank you very much. That is excellent testimony, and the longer version of your response, without objection, has been included in the record.

To summarize what you did and what you found, in response to our request to make an assessment of whether or not these techniques were being used, you prepared a survey of the Fortune 500 companies plus 50 utilities——

Ms. **Kolsrud**. That is correct.

Mr. **Gore** [continuing]. Plus 11 labor unions. Right?

Ms. **Kolsrud**. Yes, Mr. Gore.

Mr. **Gore**. You very carefully prepared a questionnaire and addressed it to the chief executive officer of the company and hoped it would be referred to the medical officer with expertise in the area, and you made a decision that you would get a better response if you afforded them, the companies, the opportunity to respond anonymously.

Then you tested the questionnaire, and you scientifically designed it, calibrated it in response to your test, and then sent it out to all of these companies. Is it fair to say that you really did not expect to find that any of these companies were currently using genetic screening?

Ms. **Kolsrud**. I do not think we had any preconceptions about whether or not they were. There had been, of course, an article in the New York Times suggesting that testing was going on. On the other hand, there had also been a considerable number of statements that it was not going on.

Mr. **Gore**. The prevailing conventional wisdom was that it is really not going on, it is premature.

Ms. **Kolsrud**. The statements that were made would support that, yes.

Mr. **Gore**. Is it fair to say that you were surprised to find that six companies were presently conducting such testing programs? I know that is not a scientific question and you are used to answering scientific questions but——

Ms. **Kolsrud**. I do not think we were surprised or unsurprised, although perhaps I should let Dr. Rose comment on that as the person most involved in the survey. In fact, that is a question I have not asked her and I would be interested in the answer.

Mr. **Gore**. Yes.

Ms. **Rose**. In the design of a survey, one must determine the size of the sample to be surveyed. One factor in sample size determination is an estimate of the occurrence of the factor being investigated.

Mr. **Gore**. Right.

Ms. **Rose**. To get that estimate, we did a quick survey of CDC-certified laboratories to ascertain the approximate number of companies for which they were conducting biochemical genetic or cytogenetic testing. From this survey, we knew such testing was occurring in industry.

Mr. **Gore**. Yes.

Ms. **Rose**. Whether such testing was being done to test individuals that companies knew were diseased, or whether it was to test healthy, asymptomatic individuals, we did not know.

Mr. **Gore**. Let me ask the question in a little different way: Were you surprised to find that 59 companies on the list were planning to undertake such testing programs in the near future, in the next 5 years?

Ms. **Kolsrud**. Fifty-nine is roughly 10 percent——

Mr. **Gore**. Sixteen percent, I believe, of the respondents.

Ms. **Kolsrud**. It is 16 percent of the respondents but 10 percent of the Fortune 500; you will recall that we do not know how well the data from those who responded represents the population as a whole.

Mr. **Gore**. Now wait a second. You had, out of the list you surveyed, you had 366 respondents. Correct?

Ms. **Kolsrud**. That is correct.

Mr. **Gore**. Fifty-nine of those 366 indicated that they were planning to—either were currently using it or were planning to use it within the next 5 years. Dr. Rose, clarify this point for me.

Ms. **Rose**. The 16.1 percent, the 59 companies, refers to future users only; not to whether they currently are using it.

Mr. **Gore**. Yes, I see. Well, so——

Ms. **Rose**. It is possible that some of the respondents who are potential future users—may be currently using it also.

Mr. **Gore**. OK. Well, that seems like a high number to me, 16 percent of the sample group responding indicating plans or intentions to use this technique in the next 5 years.

Ms. **Rose**. It certainly indicates that it is not an area unknown to industry.

Mr. **Gore**. Yes, yes. All right, now, I have some questions on the survey itself and then I want to ask about some of the implications of it

First of all, it was truly an anonymous questionnaire. There were no marks on the questionnaire that would enable you to trace back to the respondent.

Ms. **Kolsrud**. Yes, there was no hidden way in which we could do that. It was truly anonymous.

Mr. **Gore**. I understand that one of the industry trade groups tried to raise suspicions among their members by falsely stating that there was an identification number in the corner of the questionnaire, or alleging that such was the case. Is that correct?

Ms. **Kolsrud**. Yes, that is correct. There was no attempt to identify it.

Mr. **Gore**. There was no attempt to identify the questionnaire.

Mr. **Karny**. There is a mark that the contractor—NORC—put on for its own use which simply indicates that this questionnaire was of a particular type and sent out at a particular date. The exact same mark was on every questionnaire.

Mr. **Gore**. It is the same on every one?

Mr. **Karny**. Yes.

Mr. **Gore**. Therefore, there is no different number on each one.

Mr. **Karny**. No.

Mr. **Gore**. Well, maybe that was the result of a misunderstanding.

Ms. **Rose**. I think it could have been. I would have been surprised if a corporation might not have questioned what that mark meant.

Mr. **Gore**. I see. All right. We will explore that later, then. That may be a misunderstanding.

Now was there anything in the data to explain why fewer organizations were utilizing the tests now than in the past?

Ms. **Kolsrud**. To my knowledge, no, but maybe Dr. Rose or Mr. Karny has elaboration on that.

Ms. **Rose**. No, there is no way to get at that data unless the company sought to explain that in the comment section. To the best of my understanding, such information was not provided.

Mr. **Gore**. Now there were 50 companies who said that they anticipate using screening in the near future. Does this survey provide additional details as to whether these companies are presently actively seeking to develop valid screening methods? Did the survey disclose such data?

Ms. **Rose**. That analysis has not been run but could be run.

Mr. **Gore**. Could be run from the survey results?

Ms. **Rose**. Yes.

Mr. **Gore**. Well, we would be interested in the results of that analysis.

Now on table 4 in your testimony, entitled the "Purpose for Conducting Biochemical Genetic and Cytogenetic Screening," you cite "routine" and "research" purposes. What does the "other" category mean?

Ms. **Kolsrud**. I believe that category is simply any other category than those two possibilities, and was undefined. Is that correct?

Ms. **Rose**. Yes; that is correct. One such possible response for "other" could be if they were testing techniques, for example, and chose not to consider that as research but "other."

Mr. **Gore**. OK. Was there anything in the survey data telling whether biochemical and cytogenetic testing was being used to screen prospective employees?

Ms. **Rose**. No, there was not. The inference, I believe, as Dr. Kolsrud has suggested, is that biochemical genetic screening most probably would be used more in preemployment than in post employment situations. However, it is conceivable that a corporation may be developing a new product that they had not used in the past and desire to screen their existing work force for biochemical genetic aberations. Therefore, it could be used in situations other than preemployment.

Mr. **Gore**. OK. All right. However, some of it was being used for screening prospective employees?

Ms. **Rose**. We do not know that answer.

Mr. **Gore**. The respondents did not make that clear.

Ms. **Kolsrud**. That is correct.

Mr. **Gore**. It is possible, though, to screen prospective employees to find out whether or not they are genetically predisposed to be more or less susceptible to an occupational hazard, is it not?

Ms. **Kolsrud**. It is possible to apply these tests. Whether one draws the conclusion that they are in fact more or less susceptible depends upon the validity and the reliability of the test.

Mr. **Gore**. Now correct me if I am wrong but it seems to me there are two categories of issues. The first is, are the tests valid? Are they reliable enough to justify their use? The second category of issues is: If you assume that they are valid and reliable enough to use, what are the legal and ethical implications of their use? Would you agree with that breakdown?

Ms. KOLSRUD. I think that is a very clear statement.

Mr. GORE. All right, now, leaving aside for the moment the first question about validity and reliablity—I want to come back to that—let's talk for a moment about the implications. The first implication of an accurate test would be, at what point is it invidious discrimination to deny a person a job on the basis of their genetic heritage? Mr. Karny, you are the legal expert at OTA working on these issues. Can you give us some guidance on how to frame that issue?

Mr. KARNY. I will try. It is a very difficult issue and the law is unclear on this point. We have to look to existing case law and statutes in the areas of title 7 of the Civil Rights Act of 1964 and the Rehabilitation Act to provide some guidance, there have been no cases directly on point.

We are at the point in the project of trying to pull together this analysis, so to a certain extent it is premature to try to scope this out here. However, basically one would look at the impact of the tests on particular racial or ethnic groups and then examine the business purposes or other justifications for using those tests. Those are basically the two approaches taken in applying title 7 to a situation where there may be discrimination.

Mr. GORE. Therefore, there are no clear guidelines yet?

Mr. KARNY. That is correct.

Mr. GORE. This is just a frontier area of the law and there are no clear guidelines.

Mr. KARNY. Well, I think there are guidelines to the extent that we can look at existing standards, for example, under title 7 and then try to apply them to this situation. One could argue about their applicability and what additional factors would be necessary to find discrimination.

Mr. GORE. Now wait a second. What you are saying in effect is that there are guidelines to the extent that current laws prohibit the use of certain genetic markers in employment denials.

Mr. KARNY. No, sir. I am saying that current law sets forth certain definitions of discrimination and standards and criteria for assessing a particular situation in which to apply these standards. These situations generally arise out of various job-related tests, including medical examinations, but none of which have been specifically involved, to my knowledge, with genetic testing. Therefore, in the case of applying these standards and criteria to genetic testing, we are really at the point of looking at past standards in other precedents and then arguing by analysis.

Mr. GORE. All right, now, the second implication, assuming an accurate test, would be to what extent would a company be encouraged to shift resonsibility for an unsafe condition to the employee instead of assuming responsibility to remove the hazard for all of the population of workers exposed to that hazard. Is that correct?

Mr. KARNY. That would be another question.

Mr. GORE. What other issues would you put in that category, if you assume a valid, reliable test?

Mr. KARNY. For example, one might look at how the tests would actually be conducted. In other words, what information should an employee be given about the test and about the uses that might be made of the data; who should have access to the data in the medical file; what does one tell an employee with regard to the results of the test?

Mr. GORE. All right. Let's talk about reliability for a minute. We have six companies on the Fortune 500 list that are currently using these techniques. We have 59 more that anticipate using them within the next 5 years. Are these tests sufficiently reliable to justify their use for preemployment screening, for example, assuming that that is a use to which they are put? Are they sufficiently reliable to be used for that purpose?

Ms. KOLSRUD. Let me just for the record distinguish between reliability and validity, reliability being the degree to which a test consistently measures the same thing, validity being whether or not the test is measuring what you think it is measuring, so these are two very different measures.

With regard to your question, however, I have to say at this point that our analysis of that issue is really incomplete and therefore we simply cannot make comments about it at the present time because any answer might be misleading.

Mr. GORE. OK. All right. We have had testimony, we had testimony in the October hearing that the validity of the tests is quite poor and that the number of false negatives and false positives are such that it is quite likely that someone denied employment on the basis of such a test is the victim of an irrational act. However, you do not have enough information at this point on which to base an answer to that question. Is that correct?

Ms. KOLSRUD. That is correct. We feel we should finish our analysis before we leap into that water.

Mr. GORE. Well, Dr. Ernest Dixon, who testified in October, stated with respect to cytogenetic screening, and I quote:

> Without going into any of the specifics of testing techniques and difficulties therein, it is fair to say that all of the studies done thus far are seriously flawed due to the complexity and inadequate control of the many variables—improper experimental design, incorrect epidemiologic interpretation, inadequate validation, lack of standardization, nonreproducibility, and genetically irrelevant end points. In some cases, studies have been undertaken to develop a base line of the frequency of aberrations in nonexposed groups. However, I know of no instance in which a reliable conclusion has resulted.

Dr. Rose, do you have any opinion on this question?

Ms. ROSE. We do have the data in from two contractor reports, and have drawn our tentative conclusions, however. I think it would be best at this time to wait until the OTA panel of experts has a chance to review and comment on our draft report before we say something for the record.

Mr. GORE. Well, could you give us your tentative conclusions? This is a new area and it is moving so rapidly, I hope that your referees will forgive me pressing you to give a tentative conclusion. We will give you an opportunity to correct the record or change it.

Let me ask it this way: Could you give me your personal opinion, not in connection with your official position?

Ms. ROSE. My personal opinion is that there is much confusion left in this area, both in terms of cytogenetic testing and biochemical genetic testing, primarily in terms of the lack of epidemiologic studies. Such studies require large populations to be studied over an extended period of time. In the case of biochemical genetic aberrations the incidence rate is small, so that the number of employees to be screened would be immense. Epidemiologic studies can be retrospective or prospective in time. Retrospective studies are currently difficult to do because of the lack of adequate industry records on this population. Prospective studies which look ahead in time, take time to do.

Mr. GORE. Well, I appreciate that opinion.

The testimony that we have received leads me to the conclusion that this is, as yet, akin to a black art and that it is really very tentative and premature. Nevertheless, companies are rushing headlong into this technique, or apparently many of them are ready to move quickly into this area.

Mr. Karny, let me ask you about the legal pressures on a company to use these techniques, even if the validity is at least questionable. What incentives under the law does a company have to use a test of marginal predictability and utility? Is it just to avoid liability?

Mr. KARNY. I think that is one aspect of it. The law, and most particularly the Occupational Safety and Health Act of 1970, places a responsibility upon the employer to maintain a safe workplace. Given that responsibility, an employer might very well do a number of things besides the very obvious remedies of simply removing hazards or limiting the effects of hazards.

For example, if the employer's medical personnel believed particular medical tests had high predictive value, the employer could use those procedures to identify individuals who may have particular health problems and then attempt to remedy those problems. One might argue legally and ethically that the employer would have that obligation and, given that perspective, the employer might examine any number of medical techniques that would supposedly identify "high risk" employees so that preventive measures could be taken.

Mr. GORE. Now, Dr. Kolsrud, you have experience at OTA in examining the progress of a variety of different scientific areas, scientific developments. I would like to get from you some indication of how quickly the developments in this area are moving. I know it is a general question but my impression is that the tremendous amount of attention being focused on genetics and biochemistry is producing a rapid accumulation of knowledge, much of which is transferable to this particular subcategory of genetic screening, and that as a result of that information fallout, the progress in this area is moving along pretty rapidly. Is that your opinion?

Ms. KOLSRUD. Mr. Gore, I would first say that the progress in the field of genetics is really extraordinary. I think Leslie Glick of Genex recently stated that already the predictions that were made a few years ago are invalid. It was thought that we would not have insulin, inteferon, and so forth anywhere near the level of development that we have them at the present time.

Therefore, in the area of recombinant DNA, cell fusion, and similar advanced genetic technologies, progress is truly astonishing. I think that many of these advances lead to problems, as you have stated. In part, the problems arise because technologies are being rapidly developed which provide us with new capabilities. We have no ethical guidelines to tell us how or whether to use these capabilities because we have not had to face the questions that are being posed by the potential of these new technologies ever before. They are completely new possibilities. Therefore, it is not surprising that we do not have guidelines for them. In the past, technology developed slowly enough that it was possible for society to evolve with it, and develop ethical guidelines as it went along.

Genetic engineering, however, is bringing us a whole host of new possibilities, of which screening of course is only one. There is gene therapy, and many other possibilities relating to relationships between people, the environment and other organisms, and our responsibilities for those relationships.

Therefore, my overall answer to your question is yes, events are occurring extremely rapidly in the general field of advanced genetics. The degree to which they will impact on this particular area of screening is difficult to predict but certainly they are applicable and are likely to have some effect.

Mr. GORE. Well, that is a most impressive answer and I certainly agree.

Dr. Rose?

Ms. ROSE. Yes; I want to add, that we should keep in mind the setting in which these studies need to be conducted to obtain the answers to the questions you are asking? It will be in an occupational setting. It should not go unnoticed from this report that more industries reported testing in the past than currently.

Mr. GORE. However, more still report anticipating using it in the near future.

Ms. ROSE. I think it would behoove us to look at what this change is about. I suggest the way we are going to get the answers is from industry and Government and academia working together. The reason for the current downtrend and the anticipated increase is worthwhile looking at and examining. What was that cause for the decrease and what are their reasons for the anticipated increase? The industrial setting is the setting where we must conduct the studies. The atmosphere in which to conduct such studies should be addressed and acceptable to all parties concerned.

Mr. GORE. Yes; well, I am convinced that the Congress has to anticipate these legal and ethical dilemmas before they are so full-grown that we have trouble wrestling them to the ground, and now is the time to look at them in my opinion. We may have to consider in the next few years a law defining what is a permissible basis for excluding someone from the work force as a result of genetic screening.

It is currently declared to be irrational and morally wrong to exclude someone from the work force because he or she has black skin or because a person is male or female, in most settings. However, if someone has a genetic makeup that means they are 10 percent more susceptible to an occupational hazard in a given industry, does that justify a refusal to hire that person on the basis of that person's genetic heritage? We do not have an answer to that yet, do we? Any of you want to volunteer an answer?

Ms. KOLSRUD. I would say it is fortunate that is a congressional and not an OTA question.

Mr. **Gore**. Well, I do not agree with you. [Laughter.]

Well, the answers are going to be difficult, of course, but we have to start considering them now and OTA was set up in order to give the Congress early warning of issues arising from the progress of technology. Your testimony and work presented here this morning, I think is a fine tribute to those who had the foresight to establish OTA and of course to your own diligence and work.

We look forward to continuing our working relationship with you all. We look forward to your larger study coming out in the fall. Great work. Thank you very much for coming here today.

Ms. **Kolsrud**. Thank you, Mr. Gore.

Mr. **Gore**. We are going to have a shift in gears and have our final panel first and then the second panel. I trust that will not inconvenience our witnesses.

I would like to call Dr. William J. McCarville and Dr. Kenneth B. Miller.

Gentlemen, would you stand and raise your right hands, please?

Do you solemnly swear that the testimony you are about to give will be the truth, the whole truth, and nothing but the truth, so help you God?

Dr. **McCarville**. I do.

Dr. **Miller**. I do.

Mr. **Gore**. Thank you very much.

Dr. William J. McCarville is representing the American Industrial Health Council, and you are also director of environmental affairs with the Monsanto Co. Dr. Kenneth B. Miller is medical director for the Workers' Institute for Safety and Health.

Without objection, the prepared statements of both witnesses will be put in the record in full at this point. Dr. McCarville, we will invite you to go first with your statement. Please proceed.

## STATEMENT OF DR. WILLIAM J. McCARVILLE, DIRECTOR OF ENVIRONMENTAL AFFAIRS, MONSANTO CO., REPRESENTING THE AMERICAN INDUSTRIAL HEALTH COUNCIL

Dr. **McCarville**. Thank you, Mr. Chairman.

I think that the earlier panel, Dr. Kolsrud and Dr. Rose and Mr. Karney, quite accurately pointed out that genetic screening can be divided into two broad categories. The first is screening for certain biochemical deficiencies and the second is screening for cytogenetic effects caused by human exposure to potential environmental mutagens. I think perhaps this is some of the source of what seem to be contradicting data that are emerging in the course of the hearing in October and perhaps even today.

Your staff, Mr. Jensen, very kindly furnished me with a copy of the record from the October hearings, and I noticed that much of the discussion held at the time concerned itself with the classical screening for biochemical deficiency. Consequently, I will not dwell on them today except to say that such enzyme deficiencies as G6PD, glucose 6 phosphate dehydrogenase; and methemoglobin reductase could result in clinical findings of anemia, abnormal hemoloysis, cyanosis in workers receiving exaggerated workplace explosures to certain classes of chemicals.

Now these biological genetic traits have been quite sufficiently developed so that they can be used in clinical testing to identify individuals either with a genetic disease or with a trait to a genetic disease. However, as of this date, even though there has been considerable work done on them in the past, these tests have not become part of the general practice of good occupational medicine.

As an example, elevated levels of methemoglobin are generally not observed in routine of periodic physicals of workers exposed to the classes of chemicals I mentioned earlier, a fact that probably means that the exposure levels are so low that sensitive individuals are not even being affected. Thus, in the absence of any clinical findings, if one were to identify those sensitives by some genetic screening, by chemical genetic screening, and to either remove them from the workplace or to prohibit them from certain jobs in the first place, it would not seem to be of much benefit either to the worker or to the company, for that matter. This may be one of the things that we are seeing here developing in the study, saying that certain tests that were done in past are not being done today.

Now the second category of genetic screening—that is, the screening for cytogenetic effects of exposure—has been and continues to be the subject of considerable debate among scientists. For example, they cannot agree if these tests furnish anything much more than a biological end point, the significance of which is unknown at this point in time.

Now the two most commonly measured end points in cytogenetic research programs are sister chromatid exchange—so-called SCE's—and chromosomal abnormalities. In both cases the measurement is made on mature human lymphocyte cells. In the body these do not reproduce to form new cells but they can be removed from the body and forced to divide by artificial means. The techniques to force cell division outside the body in themselves, for example, can influence the frequency of the SCE's. Therefore, a determination of a background frequency of sister chromatid exchange must then be recognized as not a true spontaneous frequency but rather the frequency of otherwise untreated cultures.

The use of chromosomal abnormality measurements as an indicator of exposure to radiation has been known for more than 20 years. In fact, the great majority of data on aberration frequencies in human populations has been generated in cases of known radioactive exposure. The reason for this is that until the existence of a relatively few radiomimetic chemicals was recognized, radiation was the only clear-cut chromosome-breaking agent known.

SCE measurements, on the other hand, are not a good indicator of radiation exposure but in animal studies and in research programs using human lymphocytes, have been shown to be a potential indicator of exposure to certain chemicals including, for example, chemotherapeutic agents. In this latter SCE's have been used in one recently published study to monitor DNA damage and repair in patients receiving chemotherapy for malignant disorders.

Although research in chromosome aberrations has been in progress for, as I said, approximately 20 years and in SCE's for something less than 10 years, much of the progress has been in methodology and in determination of the confounding factors which can affect the precision of the measurement as well as its accuracy.

This was described earlier by the previous group. For example, some of these confounding factors might be the general state of the individual's health, medication a person might be taking at the time, smoking habits, et cetera, et cetera.

For example, in SCE's it has been shown quite recently in studies at the Lawrence Livermore Laboratory in California—studies done on the same individual over time—that the background frequency variation can be quite large and that the variation between individuals would be even larger. It has been found to be even larger. This means—and I think Dr. Rose pointed this out earlier—that very large sample sizes are needed in order to detect differences between an exposed population and controls.

It is safe to say that the chromosome abnormality measurements are sufficiently sophisticated so that they can be used as a virtual dosimeter for radiation exposure, and the genetic measurements have been shown to correlate well with physical measurements of exposure levels. In contrast, there is almost a complete lack of a data base that would allow lymphocyte SCE assays to be interpreted as more than an indicator of chemical exposure in a human population.

The American Industrial Health Council (AIHC) has since its inception advocated the best use of science in identifying and classifying health risks in the workplace and in the general population resulting from industrial exposures. Here may be a reason—and it is speculation, Mr. Chairman—one of the biggest problems that we are facing today in trying to determine whether or not a material represents first a hazard and then a risk, either in the workplace or in the environment, is the inability that we have to translate the results of animal testing to potential human effect. If we were to have a validated direct assay which could bridge this current knowledge gap in attempting to extrapolate animal data to humans, it would be of incredible value. Maybe this is, as I said, speculation but perhaps this is a reason why a number of your responses, your OTA responses, indicated that people were looking at cytogenetic screening and, as someone said earlier, apparently seeming to rush into an uncharted technology, because it does potentially offer—it is one of a number of things that people are looking at to potentially offer this bridge in our knowledge gap today. Because it offers this potential, we in the AIHC would applaud and encourage continued research in the first.

It must be remembered, however, that at this time the question of the significance of the chromosomal aberration or the SCE results in terms of future health of an individual is unanswerable. Additionally in the case of SCE results, even their implications to the health of a population are unknown.

Continued study at the basic research level, coupled with a broad-based epidemiological study of an exposed normal population may ultimately establish ranges for the frequency of cytogenetic end-points in both individuals and populations, and give some insight into the clinical consequences of these end-points, if any. In the meanwhile, the determination of the frequency of the end points in an exposed population as compared with the frequency in an unexposed, matched, control population is useful in building a data base on the utility of cytogenetic end-points as an indicator of exposure.

Thank you, Mr. Chairman.

Mr. GORE. Thank you very much. We will hold our questions until Dr. Miller has completed his testimony.

Dr. Miller, please proceed.

## STATEMENT OF DR. KENNETH B. MILLER, MEDICAL DIRECTOR, WORKERS' INSTITUTE FOR SAFETY AND HEALTH

Dr. MILLER. Thank you, Mr. Chairman. I want to thank you for giving the opportunity to testify here this morning, and I would like to say that I am testifying on behalf of the Workers' Institute for Safety and Health, which is a nonprofit corporation which deals with safety and health issues on behalf of the labor movement in this country. I am also speaking as a clinician and physician involved in the diagnosis and treatment, and, as an individual, in dealing with occupational diseases as my specialty.

As our understanding of the basic biologic determinants of disease expands due to these rapid increases in our analytic and technologic prowess, difficult scientific, ethical, and societal questions emerge. These uncertainties grow and proliferate almost exponentially as some struggle to find applications for methodologies which have been developed in one corner of the scientific universe without the intention that these methods be applied to other spheres wherein the same predetermined set of underlying assumptions, conditions, and influences can be said to be in effect.

Such leaps of faith from laboratory to societal applications can produce profound and sometimes disastrous ripples in the waters of our collective well-being. In my view there can be no better example of this than the use of cytogenetic "screening" methods to effectively bar certain segments of society from poisonous occupations. As a physician involved in the identification and prevention of occupational diseases, I find myself deeply concerned and perplexed by the use—and vast potential abuse—of genetic screening as a purported preventive measure to protect industrial workers from the expected pathophysiologic responses to toxic substances.

In my testimony I would like to address myself to the fallacious scientific underpinnings of such practices and to further elucidate the darker potential outcomes and effects upon our society before those of us in the scientific community find ourselves, as Albert Einstein once did, protesting the misuse of an idea and a technology whose misapplication can breed individual and collective injustice and discontent.

As medical director of the Workers' Institute for Safety and Health, and in my previous academic positions in the environmental sciences laboratory of the Mount Sinai School of Medicine and the Department of Social Medicine at Montefiore Hospital in New York, I have been deeply involved in medical screening intervention programs for occupational diseases. As such, the benefits and obvious deficiencies of such programs are issues with which I have become intimately familiar, as I have been responsible for these programs. I have often searched for guideposts in the implementation of large-scale programs, where the very fact of any medical intervention immediately triggers certain resultant problems or concerns.

The most well-accepted guideposts or principles for any type of medical screening are those of Wilson and Jungner in 1968, in which they stress the need for a demonstrated benefit to the individual with little potential for harm. Additionally, a clear definition of what the disease state is and the natural progression of the disease must be firmly in hand so that early intervention and treatment may influence the prognosis in a favorable manner.

These principles are implicitly considered when one is, for example, screening individuals for colon cancer with tests for blood in the stool because the disease and the benefit from this early intervention is clear. The only remaining issue is how soon and with what level of predictive value the particular method effectively saves lives.

As Mr. McCarville has just stated, in the case of genetic screening, however, there is no known disease. The natural progression from chromosomal differences to disease is not documented and the potential harm to any individual may in fact be greater than the hypothetical benefit. This discordance between the principles of Wilson and Jungner and the practice of genetic screening exists because the basic scientific validation necessary for the application of such methods of cytogenetic screening is simply insufficient and perhaps misguided.

The detrimental ethical, moral, and regulatory spinoffs of this kind of inherently discriminatory practice have been explored and presented in numerous contexts and fora. As will be shown later, they provide ample justification for restriction and/or abolition of such practices. However, as scientific and technologic arguments often provide the raw materials for regulatory decisionmaking and rational policy approaches, the unsupported biologic assumptions implicit in the application of cytogenetic screening of workers exposed to toxic and carcinogenic substances require further examination.

I would like to speak a little bit about cancer now. Given our present understanding regarding the development of cancer, the use of genetic screening to identify "hypersusceptibles" is based on the unsupported assumption that chromosomal damage in an individual places that particular individual at a greater risk for the development of cancer. There is wide variability, as Mr. McCarville has pointed out, in an individual's response on these tests.

To my knowledge, to this day there is no study that has adequately followed individuals with chromosomal aberrations to explore their cancer experience in comparison with that of individuals without chromosomal aberrations. Given the high background rate of chromosomal breaks in the general population, the only useful statement that can be made using this technique is in its reference to population in which higher rates of these abnormalities compared to controls may be used to identify certain populations at risk. This policy serves only to identify a potentially harmful substance in an exposed population, not an individual worker, and cannot specifically state who within that population will develop the disease.

Thus, in my view, the distinction between susceptibles and nonsusceptibles becomes meaningless when you have to counsel an individual or patient as to their own individual outcome or their placement in an unexposed job category or their probability of developing the disease in question. The use of such nondiagnostic testing methods thus creates uncertainties in response and intervention for those of us who must intervene, due to this artificial designation of susceptibility.

Should these susceptibles be screened for the development of cancer? If so, screened for which kind of cancer? For how many years should a person be watched by their physician? Can those who are designated as "nonsusceptibles" be assured that they are at no greater risk to develop cancer than the others? Can "nonsusceptibles" turn into "susceptibles" given an ongoing exposure and, if so, then isn't everyone who is exposed at risk?

The insufficient answers to these questions point out the gaps in our knowledge and our inability to make the most basic of health-related decisions based upon these methods. While further research is required in order to complete the picture, cytogenetic screening can only be justified in my view, if the usual human subject protections and informed consent guidelines are in place and adhered to and if the rights of the workers involved are clearly stated and guaranteed.

Needless to say, to me the whole concept of susceptibility appears to sanction the continued carcinogenic exposure of presumed nonsusceptibles under the false security blanket of supposed resistance to the development of disabling and fatal diseases, while potentially falsely alarming and socially dislocating those who have been needlessly labeled as "hypersusceptible." For this, there is no scientific justification. Moreover, there can be no moral justification, as no reliable individual or societal benefit can be realized through this process and the costs may fall heavily upon those who have been so artificially categorized. Additionally, the locus of responsibility can be glibly shifted to the genetics of the worker, thus deflecting the attention that might be paid to the employer's inability or unwillingness to make the workplace safe for all those who trust that their health will be protected on the job.

Regarding the use of biochemical and/or cytogenetic techniques as a preemployment screening tool, the same deficiencies in logic and analysis emerge. It is important to distinguish between the genetic makeup of an individual, called the genotype, and the expression of that genetic trait in a biochemical or physical outcome, known as the phenotype. It is often the case, as with sickle-cell trait in blacks, for example, that if a heritable difference is present its clinical significance is of no importance. Those with sickle-cell trait have not been shown to be at greater risk necessarily to develop hemolytic anemia than those with the usual genetic pattern of hemoglobin.

Still, proponents of preemployment genetic screening cling to the assertion that they are preventing disease by prohibiting employment. The social costs of unemployment incurred by the discriminatory nature of this screening method far outweigh the nonexistent benefits to the health and well-being of the individual.

With other biochemical or metabolic expressions of genotype, the presence of an inciting environmental insult must often be present for the genetic makeup to express itself in clinical disease. Much attention has been paid to the use of screening methods for alpha-1-antitrypsin. In this case, the deficiency of this enzyme does in fact predispose an individual to lung disease, usually in the presence of a precipitating environmental exposure. While exposure control is an optimal strategy to protect all workers, for these few individuals with this very rare enzyme deficiency—you are talking about a small number of individuals here—removal from exposure should be implemented with the provisions of wage and seniority retention.

This does nothing, of course, to protect those who may still be vulnerable to respiratory exposures but it does point to a strategy for health promotion in the workplace without job discrimination, namely, the use of such testing methods not as a preemployment method but as a preplacement tool to identify the appropriate job category for that individual. This confers the full protection of equal opportunity statutes and union rights to already hired workers in contrast to the virtually unprotected job applicant.

Still, these scientifically divisive arguments steal the center stage from the real problems we face in protecting the health of our work force and their families who are unwitting victims of this poisoning of America. These issues do not center on the "singling out" phenomenon of "genetically inferior" workers but revolve more around those millions of workers who are daily exposed to known and identified toxins and carcinogens for whom no facile strategy of susceptibility identification and finger-pointing exists.

It is my belief that genetic screening will rarely if ever make a significant impact on the control and prevention of occupational disease, for evolution and the inevitable comingling that is inherent in the term "gene pool" renders such monocausal explanations useless. In a sense, this genetic continuum makes us all potentially susceptible, given the appropriate combination of factors.

There is no known way to tease apart this complex nature of major occupational diseases, and while we can identify only a very few genetic predispositions which affect a very small number of people, we are quite aware of the morass of chemical exposures in the work environment. As individuals who have the opportunity to impact upon the health of millions, prudence dictates that we do not become diverted by sidestream explanations of occupational disease for which there are no just and meaningful solutions, and in so doing, overlook the known and well-documented, preventable causes of death and disability which cut across the blurred lines of race, ethnic background, or familial ancestry. For though our genetics determine who we are, it is our environment that determines who and what we may become.

Thank you very much.

Mr. GORE. Thank you very much.

I take it you do not think much of these tests. Is that correct?

Dr. MILLER. Well, I do not. I feel that, if I may respond to a question you asked earlier regarding Dr. Ernest Dixon's statement, who apparently does not feel that there is much utility in using these tests, I would like to use an example that he may have had in mind which shows just how little utility there is for these tests.

In the study of benzene-exposed workers by Dr. Picciano, he looked at a group of controls, unexposed controls, and workers exposed to benzene, and found that in the unexposed controls 40 percent of the people had chromosomal aberrations, 40 percent in the nonexposed group as compared with 73 percent in the exposed group. Clearly, if 40 percent of the unexposed people have this abnormality and are not exposed, if we discriminate against them in terms of removing them from exposure we may in fact be removing someone who is not really at any more significant risk of developing the disease. With this high background rate of mutations, there really is no way at this point to use these tests in a meaningful manner, with the exception, as I pointed out, as a research tool in defining which substances and which groups of workers as a population may be at greater risk.

Mr. Gore. Well, do you agree that it is likely that the accuracy and precision of these tests will improve dramatically in the next few years?

Dr. Miller. I am not a geneticist and I am not totally familiar with the very front line of research but it is my personal opinion that because this biologic phenomenon is so common in our society, and because of the multiple causes of these kinds of effects, I do not see it as being a very useful tool in the near future.

Mr. Gore. Well, there are three thresholds before you get to the really tough ethical questions. The first is, we were told last October, "You do not need to worry about this because nobody is using it." Well, the OTA survey puts that question to rest; they are using it and many more now anticipate using it in the near future, so the questions have to be addressed.

The second threshold is, you do not even have to get to the tough ethical, moral questions because these tests are not reliable. You ought to just rule them out because they by nature are unfair and discriminatory because they make up a "black art," and so do not base employment decisions on them. However, if you assume that, first, they are going to use them and, second, they are going to be improved to the point where they are accurate within acceptable parameters, then you get to these really tough questions about when is it fair to use them as the basis for employment decisions and when is it not. When does a company have the right to stop improving its workplace environment and instead weed out people that are going to be more susceptible?

However, so far you are satisfied that they are so unreliable that you are still at that threshold. Correct?

Dr. Miller. As a scientist, yes, that is correct. I feel that they are unreliable scientifically, so I do not see their utility in terms of an individual, in terms of my dealing, for example, with a patient who has been found to have this abnormality. What do I tell that patient? Do I tell him he is going to go on to develop cancer or is he not going to? Do I screen him for cancer? What do I do?

Mr. Gore. Yes.

Dr. Miller. Therefore, they are nondiagnostic. They do not really, significantly contribute to your information from a clinical point of view. Now in terms of a research point of view, I think that there may be some validity in looking at and further clarifying this picture, and developing the kinds of answers to the questions that you are asking in terms of their validity.

Mr. **Gore**. Dr. McCarville, the same question: How do you respond?

Dr. **McCarville**. Well, first of all let me say, Mr. Chairman, that much of what Dr. Miller just finished saying, I would echo very strongly. The cytogenetic testing techniques—and again I differentiate between the biochemical genetic testing techniques—at this point in time offer, No. 1, no clue to their association with any clinical findings, certainly no clue toward the future health of any individual, and at best offer only a very basic research approach to a very complex problem that I mentioned earlier, and maybe even not a good approach but it is an approach to the idea of being able to observe an effect directly on a human cell as opposed to observing an effect on a rodent and trying to translate that to the human.

In terms of today's state of knowledge, the best that can be said about cytogenetic screening—and I think Dr. Dixon, as you quoted him earlier, was referring to cytogenetics when he pointed out that there is no predickivity of the results of cytogenetic screening—there is at best an indicative result.

Mr. **Gore**. OK. Let me interrupt you there because I think there is some confusion about terms here. What both of you have just been discussing is cytogenetic screening. Now that differs from biochemical genetic screening, correct?

Dr. **McCarville**. Which is far more precise and far more accurate.

Mr. **Gore**. All right. Now let me give my definition of the difference between the two, and let you two correct it: Cytogenetic screening consists of the analysis of chromosomes in individuals at the point of cell division, looking at the nature of the chromosomes in order to detect some damage to the chromosome or some abnormality in the 46 chromosomes or 23 pairs of chromosomes. Correct?

Dr. **Miller**. Yes, it is looking for chromosome breakage or other abnormalities or other exchanges, right.

Dr. **McCarville**. However, it should be recognized that it in itself is an artificial observation, since the cells that are being examined are peripheral lymphocyte cells which do not by themselves, in and of themselves, subdivide in the body. They must be removed from the body and, if you will, "cooked up" with chemical reagents which are not present in the body in order to force that cell to do something which they would not naturally do.

Mr. **Gore**. Yes. Now by using that technique, one can establish whether or not an individual probably has chromosomal damage or chromosomal abnormality.

Dr. **McCarville**. No, sir. I think that would be a leap of faith to go that far.

Dr. **Miller**. I agree.

Mr. **Gore**. What does it establish?

Dr. **McCarville**. It is an indicator of an effect, and that is about as far as you can go.

Mr. **Gore**. What does it establish about the individual?

Dr. **McCarville**. Nothing.

Dr. **Miller**. Nothing.

Mr. **Gore**. Nothing? Well, why are companies doing it, then?

Dr. **Miller**. Well, because I think the theoretical basis—I am not from a company, obviously but if I might take the liberty to hypothesize—is that we know or we believe, anyway, that cancer is somehow related to what goes on in the DNA and the chromosomes. If we could then, for example, look at an early marker, if in fact we can pick up that chromosomes are being damaged in a particular kind of cell in the blood called the lymphocyte and we can pick up this damage early, maybe that relates to cancer. Maybe it does.

Dr. **Gore**. Does this all go back to the Ames test? Does this have to do with the Ames test? I mean, does it have to do with the assumption that a predisposition to chromosome damage implies a predisposition to other kinds of damage?

Dr. **McCarville**. Mr. Chairman, some years ago Dr. Ames introduced his test, which looked at the impact of materials on organism cells.

Mr. **Gore**. That is mutagenicity.

Dr. **McCarville**. Yes.

Mr. **Gore**. The question is off-base. I will withdraw it.

Dr. **Miller**. Now, wait a minute, sir. I think you were closer.

Mr. **Gore**. All right.

Dr. **Miller**. The particular test we are looking at also looks at the cellular level but at this point in time it certainly does not look at it in attempting to determine its predilection for any kind of later disease.

Mr. **Gore**. OK. Now most of the companies in the OTA report were not using cytogenetic screening but they were using biochemical genetic screening, which is a different kind of analysis. There you are not looking for chromosome damage or chromosome abnormality. Instead, you are looking for clues in a biochemical analysis that will tell you something about the genetic makeup of the individual. Correct?

Dr. **Miller**. It is sort of the other way around. It is that is that the genetic makeup when a person is born creates a deficiency, let's say, in a certain enzyme which makes a person then potentially less capable to cope with a particular exposure so, in other words, the genetics of a person will go ahead and determine this lack of an enzyme and that lack of an enzyme is an aberration of the normal metabolic process.

Mr. **Gore**. Therefore, you are looking for very specific abnormalities. You are not looking for some generalized indicator of an effect, as in cytogenetic screening. You are looking for specific indicators of specific problems. Correct?

Dr. **Miller**. You can find this in nonexposed people, for example. The exposure does not determine this; the genetics of the person determines this. A person does not have to be exposed to have alpha-1-antitrypsin deficiency. They are born with that inherited, congenital, if you will, deficiency of an enzyme. Those deficiency diseases are rather rare in our population. Very, very small numbers of people have that particular one, for example.

The other hooker in this is for example, with sickle-cell trait in which a person has a genetic trait but that genetic trait is not expressed in any metabolic deficiency that we can pick up. We can pick up that their genes look a little strange, their hemoglobin looks a little abnormal, but they suffer no clinical consequences of this trait being present in their genes.

Mr. **Gore**. Isn't it true that monoclonal antibody diagnostic kits may greatly improve biochemical genetic screening in the very near future?

Dr. **McCarville**. I am sorry. I am not a clinician. I cannot speak to that.

Mr. **Gore**. Dr. Miller?

Dr. **Miller**. Well, monoclonal antibodies originally were diagnosed in patients, for example, with multiple myelomas, those sorts of diseases. I am not familiar with the frontier of research and how they can be used in terms of screening out individuals. I am not aware of any particular disease state that is due to exposure that is the result of a lack of monoclonal antibody.

Mr. **Gore**. Well, the work of the subcommittee leads us to believe that new diagnostic techniques are likely to be available fairly soon.

Now moving away from the cytogenetic screening and into the biochemical screening, if one makes the assumption that there will be an accurate way to determine that an individual is genetically predisposed to be more susceptible to an occupational hazard, say 10 percent more susceptible to brown lung disease in a cotton mill, is that a rational basis or a defensible basis for the employer to deny employment to that individual that is genetically predisposed to be 10 percent more susceptible?

Dr. **Miller**. My response to that would be no, for two reasons. One is that it is my view that we should control the exposures down to the level of those who are most susceptible. That is one point. Second, if we are able to identify these individuals, I do not believe that we should bar them from employment. As I suggested in my testimony, I think we should find ways to employ these people and keep them employed but in a job in which, if you must continue to expose all those people who are 15 percent or 12 percent more susceptible, we assume that there is a cointinuum of susceptibility, not an absolute cutoff. That would not make biologic sense to me, that there was an absolute cutoff, and if we continue to expose the 12 percenters and the 13 percenters, then we must at least make an effort to—if there are those hypersusceptibles, if you care to call them that—that their employment rights be protected either through legislative intent or other regulatory mandates to make sure that they are not, in fact, discriminated against because of something over which they have no control.

Regarding liability that would result, even if a person was exposed, in my view, the workers' compensation system, as inadequate as it is, should protect employers because the basic agreement was that it is not the worker's fault. He brings to the place of employment who he is and he is accepted on face value for that.

Mr. **Gore**. Dr. McCarville, the same question.

Dr. **McCarville**. Mr. Chairman, in my prepared statement I used examples of biochemical genetic testing which are in hand today—the G6PD and methemoglobin reductase—which are known tests to determine proclivity toward anemia, hemoloysis, cyanosis, et cetera. These tests which are in hand today are not being used as part of the general occupational medical program because you have the lack of clinical findings of elevated methemoglobin and consequently, to go back and use a biochemical genetic screen when you do not have the symptoms in the workplace clinically to begin with, as I said, would not do the worker or the company any good if you were to use them for the purposes of either excluding a person from employment or removal from the workplace center.

Mr. **Gore**. Some are using that precise test, according to the survey.

Dr. **McCarville**. Some have used it in the past. I have not seen the results of the survey but in the transcript from last October——

Mr. **Gore**. Some are presently using it.

Dr. **McCarville**. Is that right?

Mr. **Gore**. Yes.

Dr. **McCarville**. In the transcript——

Mr. **Gore**. Would you say they are wrong?

Dr. **McCarville**. I cannot say they are wrong. I am saying what generally seems to be——

Mr. **Gore**. Would you advise your company to use it?

Dr. **McCarville**. My company does not use it.

Mr. **Gore**. Would you advise them not to if they wanted to?

Dr. **McCarville**. We have made the considered judgment it is not worthwhile using it.

Mr. **Gore**. All right. Now back to the hypothetical question: You run a cotton mill and you have a test which indicates the person applying for a job is 10 percent more susceptible to brown lung disease than the rest of your employees. Is that a valid basis for denying employment?

Dr. **McCarville**. Setting all of the legal implications aside for the moment because I do not know what they are——

Mr. **Gore**. That is a herculean task but go ahead. [Laughter.]

Dr. **McCarville**. I have to speak from my state of knowledge.

Mr. **Gore**. I understand, yes.

Dr. **McCarville**. I would say that it is not justified to set the employee aside or not employ him to begin with. I think one should make sure that a workplace is in the shape that these employees are not going to be harmed. A 10-percent difference between an individual and some sort of norm is probably not a significant enough difference to be above normal biological difference.

Dr. **Miller**. To be clinically significant is the term I would use.

Dr. **McCarville**. Yes. Sorry.

Mr. **Gore**. Well, let's make the assumption that it is 60 percent. Let me ask you this way: Rather than playing a numbers game, what would be clinically significant?

Dr. **McCarville**. Mr. Chairman, I am not a physician. I do not know what the percentage——

Mr. **Gore**. Dr. Miller?

Dr. **Mller**. Well, if you have an exposure that is making somebody sick, I would say that that is clinically significant. You know what I mean? I am not trying to be funny. I am approaching it from a clinical point of view, and that is that if a person comes in and they are having symptoms and you can, through their work history and through other techniques, decide that it is due to their work, then that to me is a clinically significant work-related problem. At that point something has to be done. In terms of trying to put the legal implications aside, I think this is where the legal intervention is necessary to protect that worker's health and at the same time his job rights, his legal rights.

Mr. GORE. Well, what is significant in terms of risk?

Dr. MILLER. That is a very difficult question.

Mr. GORE. You said 10 percent would not be significant in terms of risk.

Dr. MILLER. You are asking me to put a number in terms of risk assessment and, as I am sure you are aware, there is a whole body of debate in scientific assessment called risk assessment. I would not put it in terms of a percent sort of risk. I would put it more in terms of what we know about the risk to all individuals based on a substance identification. If a substance is shown, by whatever methods we have available in science, to be a hazard to workers, regardless of their susceptibility on this continuum I would say all of them are at risk. That is why this dichotomy between susceptibles and nonsusceptibles is artificial because if it is a risk, I believe along the biologic continuum that it is a risk to everyone. Now at what levels and how much and when will the person develop the disease—maybe some will get their cancer sooner than others—these are all individual questions which are difficult to extrapolate from population studies, and that is where we get most of our information from with the exception——

Mr. GORE. Well, the fact is that lawyers representing companies that have liability facing them are going to be advising companies to pay attention to 10 percent figures, 20 percent, at some point. We had testimony in October from the chief counsel for a railroad in this country that somewhere between 2- and 5-percent difference would, under the statute under which they operate, require them to deny employment if there was between a 2- and 5-percent elevated risk. Therefore, I do not know what the answers are but I think that the questions are going to—Dr. McCarville, did you want to respond to that?

Dr. MCCARVILLE. Only in the sense, Mr. Chairman, that if for example an employee came to a company with a known serum antitrypsin deficiency, an employer in good conscience could not assign that worker to, let's say, a workplace which is extremely dusty or whatever. That is a very, very rare situation, as Dr. Miller pointed out, but I believe over and above whatever counsel might say to the employer, the medical director might say that in his medical/ethical mode he simply could not assign a worker or agree to have a worker assigned to that workplace.

Mr. GORE. Would you two agree that other biological variables such as age, nutritional status, and lifestyle can affect the body's susceptibility to environmental insults and may in fact keep a susceptible individual asymptomatic? Dr. Miller?

Dr. MILLER. Keep a susceptible individual asymptomatic——

Mr. GORE. Yes.

Dr. MILLER [continuing].—Or make him symptomatic?

Mr. GORE. No.

Dr. **Miller**. I believe that there are other factors beside the workplace that make people sick, yes, if that is the intent of that question. I am not quite sure that is what you are asking but I think there are other contributory factors which will——

Mr. **Gore**. No; that is not the thrust of the question. I am concerned and the staff of the subcommittee is concerned that the noise level inherent in the human life cycle, just from day to day and week to week, month to month, is such as to overwhelm the predictability and the reliability, validity of a lot of these tests for susceptibility.

Dr. **Miller**. I would agree with that. As I pointed out from Dr. Picciano's study where 40 percent of the people who were not exposed still had these chromosomal aberrations, that very much supports the point you are making, that the background rate, the noise level as you called it, is very high. In the exposed group there may be a significant proportion, those 40 percent, who—they are not exposed so it cannot be due to their chemical exposure and yet in fact they may be discriminated against assuming, wrongly so, that it is their chemical exposure that is causing that.

Mr. **Gore**. For the record, do either of you know any company or organization currently conducting cytogenetic testing?

Dr. **Miller**. I am not aware of any company.

Dr. **McCarville**. Cytogenetic testing?

Mr. **Gore**. Yes.

Dr. **McCarville**. From a research standpoint, obviously there were some that responded to the OTA, so there must be.

Mr. **Gore**. Do you personally know?

Dr. **McCarville**. Do I personally, from firsthand knowledge of talking to companies?

Mr. **Gore**. Yes.

Dr. **McCarville**. I have not talked to a company that is doing it now. I have talked to people, including my own company, who have contemplated doing it in the future.

Mr. **Gore**. Do you know of any company that is doing it now?

Dr. **McCarville**. I have heard that a company in the ethylene oxide business, the medical devices business, has been doing some work. There was a study 2 years ago, a preliminary study, I believe, issued and I believe there is another one coming out.

Mr. **Gore**. All right. I have some other questions but I will hold up and recognize Mr. Walker.

Mr. **Walker**. Thank you, Mr. Chairman.

Is it reasonable to assume that we will be able to accurately isolate those who are 10 percent or more susceptible?

Dr. **McCarville**. Mr. Walker, I am not sure I understand your question.

Mr. **Walker**. What I am looking for here is, what is the level of confidence?

Dr. **McCarville**. In a biochemical test, a genetic test, or the cytogenetic tests?

Mr. **Walker**. Any of them.

Dr. **McCarville**. In the biochemical genetic tests, I think one probably could detect enzyme deficiencies in the neighborhood of 10 to 20 percent. In the cytogenetic tests, I do not think it is responsive to anything about an individual.

Mr. **Walker**. What is a reasonable basis for making occupational selection, whether they be on initial selection or anything of that type, with that kind of variable?

Dr. **McCarville**. On the basis of cytogenetic testing, again I do not think there is any rationale. In the case of biochemical, probably very little, if one knows, for example, in the workplace that there are not already clinical findings showing the existence of an exposure that would cause a clinical manifestation.

Mr. **Walker**. Therefore, that would include removal from the workplace and a number of other issues of this same type.

Dr. **McCarville**. Well, at this point in time, sir, I do not know of any genetic screening, whether it be biochemical or cytogenetic, which is being used for either hiring or promotional purposes.

Mr. **Walker**. I gather from what you are saying, though, nor should it be.

Dr. **McCarville**. Certainly I think in my testimony, Mr. Walker, I made the comment that at least in the biochemical I saw no reason, if you did not have clinical findings in your workplace, that you should use it for exclusion at all and certainly in the cytogenetic screening area there is absolutely no rational for using it.

Mr. **Walker**. Therefore, the tests can be said to perhaps give us broad guidance but no more than that?

Dr. **McCarville**. Again, in the case of cytogenetics the guidance is probably so broad that it would be difficult even to speak in terms of populations, let alone individuals.

Mr. **Walker**. Dr. Miller, you seemed to have something to say.

Dr. **Miller**. Yes; I would like to respond and maybe clear up, also, in terms of what Mr. Gore was asking earlier about this 10 percent, 20 percent, and so on. The only way you can put a percent figure on any of these biochemical tests is, say that we establish a "normal range" in the rest of us who are unexposed, supposedly, of what the enzyme level should be, and then you measure the enzyme in another individual. Say that they have 10 percent less enzyme than you or I. That does not, however, translate directly by any study that I am aware of into a 10 percent increased risk that they will develop the disease. They just happen to have 10 percent less enzyme. They may have enough to significantly continue to cope and not produce what I call clinically significant manifestations, disease, in other words. I just wanted to make that distinction and also echo what Dr. McCarville has said, which is that the level of predictability and reliability and validity of these tests are so broad that you have no idea which direction to turn. In Dr. Picciano's studies on epichlorohydrin exposed workers, in fact the unexposed controls had in the three to four group of chromosome breaks, had a greater number of chromosome breaks than the exposed workers.

Mr. **Walker**. That is all the questions I have at this point, Mr. Chairman. Thank you.

Mr. **Gore**. Thank you.

Dr. McCarville, I would like to show you a memorandum from the American Industrial Health Council, from Dr. Bruce Dixon to various members of the AIHC's committee and task forces.

It states, among other things, "The questionnaire retains most of the objectionable features of the original draft as discussed in our letter of February 12, 1982." It also states, "OTA will not ask for identifying information. The draft does contain what appears to be an identification number in the upper right hand corner, however."

Now your association was asked to review a draft of the questionnaire proposed to be used by OTA in its survey. What, then, was AIHC's intent in circulating a later confidential draft to persons who would be asked to respond in the actual survey?

Dr. McCARVILLE. Are you speaking now specifically about this memo and things——

Mr. GORE. Yes. It seems like it is designed to discourage participation in the study.

Dr. McCARVILLE. No. As a matter of fact, initially there were some copies of the proposed questionnaire that were circulated for various comments, as was mentioned earlier this morning. Subsequent to this memo, Dr. Rose and Mr. Karney and another professional—and I do not recall her discipline—came to the scientific committee of AIHC and made a presentation on what OTA was planning to do, why they were planning to do it. As a matter of fact, I think that there was a formal presentation made by OTA and then OTA asked for subsequent comments by AIHC on the questionnaire. I think at that meeting we did clear up any misconceptions that we might have had earlier. We did comment rather extensively on the questionnaire and in fact we were very pleased to see that when the questionnaire finally issued in final form, much of what we had suggested as change was indeed contained in the final questionnaire.

Mr. GORE. Then you got the confidential draft of the final questionnaire that included some changes that you had recommended, and you were given that on a confidential basis. Then you circulated that draft to all your members and told them that it was objectionable and that it appeared as if OTA was being less than candid, not leveling with them, and was using some way to trace it back, to find out what their identity was. Isn't it fair to say that is designed to discourage participation in the study?

Dr. McCARVILLE. It was certainly not intended in that way.

Mr. GORE. Well, why was the confidential final draft circulated with this memo? Let me quote to you again: "The questionnaire retains most of the objectionable features of the original draft."

Dr. McCARVILLE. We felt that the original draft—and we so pointed out in our comments—did not adequately differentiate between the biochemical genetic screening and the cytogenetic screening. There were other comments that we made. As a matter of fact, the mutagenicity subcommittee—if you will notice, one of the addressees on that particular memo——

Mr. GORE. Yes.

Dr. McCARVILLE [continuing]. Worked at some great length with the OTA group. I do not think that there was an adversarial situation that persisted there at all.

Mr. GORE. Well, there are three reasons why it appears to be adversarial. First of all, it was a confidential memo which you all took upon yourself—or Dr. Dixon did—to circulate. Second, you say it has most of the objectionable features retained, and third, you say it contains what appears to be an identification number. It is hard to escape the conclusion that you are trying to discourge participation but I welcome your effort to disabuse me of that notion.

Dr. **McCarville**. Mr. Chairman, first of all, this memo certainly was not a confidential memo.

Mr. **Gore**. The draft which accompanied it, the final draft which accompanied it. The memo says, "Attached is the revised OTA survey form."

Dr. **McCarville**. Oh, yes, and I am unaware that that was considered to be confidential.

Mr. **Gore**. Well, it was.

Without objection, we will put this memo in the record.

[Material to be supplied follows:]

AIHC AMERICAN INDUSTRIAL HEALTH COUNCIL
1075 CENTRAL PARK AVENUE • SCARSDALE, NEW YORK 10583 • (914) 725-1492

June 23, 1982

MEMORANDUM FOR CONGRESSMAN GORE

Dear Mr. Chairman:

Here are the documents regarding the AIHC review of the OTA questionnaire on biochemical and genetic screening which I promised to furnish for the record.

William J. McCarville

Enclosures

cc: Mr. James Jensen

AIHC
AMERICAN INDUSTRIAL HEALTH COUNCIL
1612 K STREET, N.W., SUITE 308, WASHINGTON, D.C. • (202) 659-0060

June 23, 1982

The Honorable Albert Gore, Jr.
Chairman, Subcommittee on
  Investigations and Oversight
U.S. House of Representatives
Washington, D.C. 20515

Re: Cytogenetic Monitoring

Dear Mr. Chairman:

At the Subcommittee hearing on June 22, 1982 you requested additional information concerning the American Industrial Health Council's efforts to assist the Office of Technology Assessment (OTA) in its studies concerning cytogenetic monitoring in the workplace. I am happy to fulfill your request.

Dr. Ann Rose, Senior Analyst (OTA), called to request an opportunity to present to AIHC a proposed study of biochemical genetic testing and cytogenetic testing in the workplace. At a meeting of the AIHC Scientific Committee on January 27, 1982 Dr. Ann Rose, Dr. Geoffrey Karny, Project Director (OTA) and Dr. Nan Newell (OTA) explained the study and distributed copies of a draft questionnaire that had been prepared by OTA's contractor, the National Opinion Research Center for use in conducting a workplace survey. AIHC was asked to comment upon the draft questionnaire. At a meeting of the AIHC Mutagenicity Subcommittee on February 4, 1982, Dr. Rose again distributed copies of a draft questionnaire and asked for comments. Counsel subsequently asked Dr. Rose whether it would be appropriate to obtain the views of member companies and was informed that those views would be welcomed. A copy of a memorandum requesting comments is attached.

On February 12, 1982 counsel responded to Dr. Rose's request with comments from members. A copy of that letter is attached. Dr. Karny responded with a letter, also attached, in which he expressed appreciation for AIHC's comments on the

The Honorable Albert Gore, Jr.
June 23, 1982
Page two.

draft and noted: "I hope that members of the American Industrial Health Council will continue to work with us on this project by commenting upon staff and contractor work product."

The original draft questionnaire was revised somewhat in response to our comments and distributed by OTA to several companies. AIHC did not understand that the reviewed draft was to be kept confidential, since it had been distributed by OTA. AIHC understood that the revised questionnaire was still being evaluated by the OTA Occupational Genetic Testing Advisory Panel. The memorandum distributing the revised draft is attached.

AIHC did not receive the final questionnaire until April 22, 1982 after it had been distributed to the companies. A copy of the memo supplying a copy of the final draft is attached. The questionnaire was further significantly revised prior to its use in the survey. AIHC did not distribute any subsequent drafts or comment further on the questionnaire.

If we can be of any further assistance, please do not hesitate to contact us.

Respectfully submitted,

William J. McCarville

William J. McCarville
Chairman, Scientific
Subcommittee

Enclosures

AIHC

AMERICAN INDUSTRIAL HEALTH COUNCIL, INC.

1075 CENTRAL PARK AVENUE • SCARSDALE, NEW YORK 10583 • (914) 725-1492

February 8, 1982

TO: DESIGNATED CONTACTS
QUANTITATIVE RISK ASSESSMENT SUBCOMMITTEE
SCIENTIFIC COMMITTEE
MUTAGENICITY SUBCOMMITTEE
SCIENCE POLICY TASK FORCE
LEGAL COMMITTEE
OSHA TASK FORCE
EPA TASK FORCE

## OFFICE OF TECHNOLOGY ASSESSMENT SURVEY OF WORKPLACE GENETIC TESTING

Gentlemen:

At a meeting of the AIHC Mutagenicity Subcommittee on February 4, 1982, Dr. Ann Rose requested comments on the attached draft questionnaire. The questionnaire, which was developed by the National Opinion Research Center in Chicago, is intended to provide information on the extent of workplace genetic screening and monitoring and on the reasons behind such testing.

Objections were raised by the Subcommittee to a number of questions. Counsel was asked to respond to Dr. Rose's request for comments on the questionnaire and on proposed methods to ensure confidentiality of responses.

Dr. Rose requested that comments be communicated to her by the morning of February 12, 1982. Comments may be sent directly to Dr. Rose at the Office of Technology Assessment, United States Congress, Washington, D.C. 20510, or to AIHC counsel, Bruce Dickson at Cleary, Gottlieb, Steen & Hamilton, 1250 Connecticut Avenue, N.W., Suite 400, Washington, D.C. 20036, (202) 828-3075.

Sincerely,

Joseph D. Irr

Joseph D. Irr, Chairman
Mutagenicity Subcommittee

Attachment

DRAFT

CONFIDENTIAL

## WORKPLACE SURVEY

A letter introducing this survey, sponsored by the Office of Technology Assessment of the United States Congress, was mailed to you last week. Your response to this questionnaire by          is most important and appreciated.

## INSTRUCTIONS FOR COMPLETING THE QUESTIONNAIRES

The questions concern biochemical genetic and/or cytogenetic testing conducted or planned by your company.

We ask about only those biochemical genetic tests which screen for particular heterozygous or homozygous genetic traits listed below, and not standard blood chemistry tests.

Cytogenetic tests are intended to detect chromosomal aberrations or sister chromatid exchange.

---

1. Is your company currently conducting biochemical genetic testing of employees or potential employees?

   Yes ___
   No ___

---

2. Has your company conducted          biochemical genetic testing of employees or potential employees in the past?

   Yes ___
   No ___

---

3. Does your company anticipate conducting biochemical genetic testing in the next five years?

   Definitely yes ___
   Possibly yes ___
   No ___

---

4. Is your company currently conducting cytogenetic testing of employees or potential employees?

   Yes ___
   No ___

---

5. Has your company conducted          cytogenetic testing of employees or potential employees in the past?

   Yes ___
   No ___

---

6. Does your company anticipate conducting cytogenetic testing during the next five years?

   Definitely Yes ___
   Possibly Yes ___
   No ___

IF BIOCHEMICAL GENETIC TESTING HAS EVER BEEN DONE PLEASE ANSWER ALL QUESTIONS. IF NOT, PLEASE SKIP TO Q. 13.

7. Which of the following have you screened for?

A. Any red blood cell and serum disorders, including sickle cell trait, glucose-6-phosphate dehydrogenase deficiency, methemoglobin reductase deficiency, alpha-1-antitrypsin deficiency, alpha and beta thalassemias Yes ___ No ___

B. Any liver detoxification systems, including aryl hydrocarbon hydroxylase inducibility, slow vs fast acetylation. Yes ___ No ___

C. Any immune system markers including allergic/respiratory disease, contact dermatitis, histocompatibility markers. Yes ___ No ___

D. Any heterozygous chromosomal instabilities including Bloom syndrome, Fanconi syndrome, ataxia-telangiectasia xeroderma pigmentosum Yes ___ No ___

ENTER IN BOXES BELOW ABBREVIATED NAMES OF ALL CONDITIONS SCREENED, AND ANSWER QUESTIONS 8 & 9 FOR EACH.

| | CONDITIONS SCREENED | | | |
|---|---|---|---|---|
| | A | B | C | D |
| ENTER CONDITION HERE. — | | | | |
| 8. Did you test . . . | | | | |
| a). routinely (e.g., yearly) or during regular/specified circumstances? | Yes ___<br>No ___ | Yes ___<br>No ___ | Yes ___<br>No ___ | Yes ___<br>No ___ |
| b) on a special basis (e.g., unusual situations such as a chemical spill)? | Yes ___<br>No ___ | Yes ___<br>No ___ | Yes ___<br>No ___ | Yes ___<br>No ___ |
| c) for research purposes, (e.g., hypothesis testing)? | Yes ___<br>No ___ | Yes ___<br>No ___ | Yes ___<br>No ___ | Yes ___<br>No ___ |
| 9. Was the decision to test ever based on employees' . . . | | | | |
| a) job category? | Yes ___<br>No ___ | Yes ___<br>No ___ | Yes ___<br>No ___ | Yes ___<br>No ___ |
| b) sex? | Yes ___<br>No ___ | Yes ___<br>No ___ | Yes ___<br>No ___ | Yes ___<br>No ___ |
| c) ethnic or racial background? | Yes ___<br>No ___ | Yes ___<br>No ___ | Yes ___<br>No ___ | Yes ___<br>No ___ |

| | |
|---|---|
| 10. Corporations make decisions in different ways. In your company who authorizes the initiation of a biochemical genetic screening program? | A. Plant Physician ___<br>B. Medical Director ___<br>C. Chief Executive Officer ___<br>D. Someone else. Who? ___ |
| 11. What factors were considered in the decision to implement a biochemical genetic screening program? | A. cost benefit analysis ___<br>B. strength of the association between chemical exposure and illness in animal studies ___<br>C strength of the association between chemical exposure and illness in epidemiologic studies ___<br>D. legal consequences of failure to screen ___<br>E. union/employee pressure ___<br>F. something else. What? ___ |
| 12. What criteria were employed in the choice of a specific test? | A. predictive value of the test ___<br>B. sensitivity of the test ___<br>C. specificity of the test ___<br>D. scientific consensus _<br>E. cost of the test _<br>F. something else. What? _ |

13. Have you screened workers for exposure to chemicals by . . .

A. chromosomal abberrations ___
B. sister chromatid exchange ___
C. detection of mutations by assaying the DNA ___
D. detection of mutations by assaying the enzymes ___
E. some other way. What? ____________________

ENTER IN BOXES BELOW SHORTENED NAMES OF ALL CONDITIONS SCREENED, AND ANSWER QUESTIONS 14 & 15 FOR EACH.

| | CONDITIONS SCREENED | | | |
|---|---|---|---|---|
| | A | B | C | D |
| ENTER CONDITION HERE — | | | | |
| 14. Did you test . . . | | | | |
| a) routinely (e.g., yearly) or during regular specified circumstances? | Yes ___ | Yes ___ | Yes ___ | Yes ___ |
| | No ___ | No ___ | No ___ | No ___ |
| b) on a special basis (e.g., unusual situations such as a chemical spill)? | Yes ___ | Yes ___ | Yes ___ | Yes ___ |
| | No ___ | No ___ | No ___ | No ___ |
| c) for research purposes, (e.g., hypothesis testing)? | Yes ___ | Yes ___ | Yes ___ | Yes ___ |
| | No ___ | No ___ | No ___ | No ___ |
| 15. Was the decision to test ever based on employees' . . . | | | | |
| a) job category? | Yes ___ | Yes ___ | Yes ___ | Yes ___ |
| | No ___ | No ___ | No ___ | No ___ |
| b) sex? | Yes ___ | Yes ___ | Yes ___ | Yes ___ |
| | No ___ | No ___ | No ___ | No ___ |
| c) ethnic or racial background? | Yes ___ | Yes ___ | Yes ___ | Yes ___ |
| | No ___ | No ___ | No ___ | No ___ |

16. Corporations make decisions in different ways. In your company who authorizes the initiation of a cytogenetic screening program?

A. Plant Physician ___
B. Medical Director ___
C. Chief Executive Officer ___
D. Someone else. Who? ____________________

17. What factors were considered in the decision to implement a cytogenetic screening program?

A. Cost benefit analysis ___
B. Strength of the association between chemical Exposure and illness in in animal studies ___
C. Strength of the association between chemical Exposure and illness in epidemiologic studies ___
D. Legal consequences of failure to screen ___
E. Union/employee pressure ___
F. Something else. What? ____________________

18. What criteria were employed in the choice of a specific test?

A. Predictive value of the test ___
B. Sensitivity of the test ___
C. Specificity of the test ___
D. Scientific consensus
E. Cost of the test
F. Something else. What? ____________________

NOW FOR SOME DIFFERENT QUESTIONS

19. Has your company conducted animal testing for chromosomal abnormalities or genetic predisposition to workplace chemicals?

Yes ____ No ____

---

20. What proportion of occupational diseases do you think are mainly due to genetic predisposition toward hypersusceptibility to workplace chemicals?

A. 5% or less ________ C. 25% to 75% ________
B. 6% to 25% ________ D. over 75% ________

---

21. What proportion of occupational diseases do you think are attributable to chromosomal aberrations resulting from exposure to workplace chemicals?

A. 5% or less ________ C. 25% to 75% ________
B. 6% to 25% ________ D. over 75% ________

---

IF ANY BIOCHEMICAL GENETIC OR CYTOGENETIC TESTING WAS EVER DONE IN YOUR COMPANY, ANSWER Q.22.

22. Has your company ever taken any of the following actions as a result of testing programs?

A. Suggested employee seek another job ____
B. Did not hire someone ____
C. Transferred employee or referred him to another job in the company ____
D. Implemented engineering controls ____
E. Recommended personal protection devices ____
F. Implemented research program ____
G. Some other action. What? ____
H. No action taken ____

---

IF NO BIOCHEMICAL GENETIC OR CYTOGENETIC TESTING HAS EVER BEEN DONE IN YOUR COMPANY, PLEASE ANSWER Q'S 23 & 24.

23. Why has no such testing been done? ____________________

24. What criteria or circumstances would be necessary for you to consider testing? ____________________

---

25. Would you be interested in testifying before the committee in the event that hearings are held?

Yes ____
No ____

---

26. We would appreciate it if you would print your name and position in case we need to clarif with you any of your responses.

NAME: ____________________ POSITION ____________________

---

Thank you for completing this questionnaire. The information you have provided will be held in strict confidence. Data will be made available in statistical form only.

---

27. If you choose not to respond to this questionnaire, please indicate your reasons below.

CLEARY, GOTTLIEB, STEEN & HAMILTON
1250 CONNECTICUT AVENUE, N. W.
WASHINGTON, D. C. 20036

(202) 828-3000

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PRINTING HOUSE
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HONG KONG

February 12, 1982

Ann H. Rose, Dr. P.H.
Senior Analyst
Office of Technology Assessment
United States Congress
Washington, D.C. 20510

Re: OTA Workplace Survey

Dear Dr. Rose:

Dr. Joseph Irr has asked us to convey to you his thanks for your taking the time to talk with the American Industrial Health Council (AIHC) Mutagenicity Subcommittee last week. We hope that the meeting was useful to you in your efforts to review the draft workplace survey questionnaire prepared by your contractor.

You have requested that we review and comment on the draft questionnaire. The time limitations that you have placed upon our review prevented us from obtaining the views of AIHC or of a wide range of companies. A number of individuals have, however, reviewed the questionnaire and this letter will set out their initial observations.

The general tone of the questionnaire suggests that the results will be used to indict genetic testing as a means to discriminate in hiring and in job placement. If our perception is shared by companies receiving the questionnaire, it is unlikely that many companies will cooperate with the survey. The questionnaire should be rewritten to remove all suggestions that it is intended to support or to test a particular theory on the use of tests.

We doubt that many major multi-plant companies will have the information you request readily available at company headquarters. The amount of effort necessary to respond will, we suspect, prompt many companies either to decline to respond or to respond on the basis of assumptions and guesses. Your survey should determine whether each response is based upon information available at headquarters, upon an in-house survey of plant sites or upon some other source of information.

In our view, your draft questionnaire would be more likely to generate a response if it was confined to the basic issues to which the study appears to be directed. You might inquire as to which studies are being performed, on whom, at whose request and for what purpose. In order to reach qualified personnel, it might be appropriate to request that companies refer questions to qualified company members of the American Academy of Occupational Medicine. You could thereby achieve some level of control over the qualifications of the respondents.

You have asked whether confidentiality concerns will be significant to recipients of the questionnaire. While we, of course, cannot speak for the individual companies to whom the questionnaire will be directed, we suspect that concerns for the confidentiality of responses will be highly significant. Indeed, we suspect that many companies will answer the questionnaire only if their identities cannot be determined.

You have suggested that your contractor needs to be able to identify respondents but has devised a method for ensuring confidentiality by retaining outside the United States borders all identifying material. We are not aware of the details of this plan and therefore cannot comment on whether it will in fact ensure confidentiality. Our experience has been that the use of a nationally recognized accounting firm to maintain confidential data is helpful in assuring companies that confidentiality will be preserved. However, the comments we have received suggest even this device will not relieve the concerns of many companies if the survey is not "blind."

We have the following comments on specific questions:

Question 1: It may be necessary to define what type and purpose of test is referrred to by the term "biochemical genetic testing." This question does not distinguish between tests performed at the request of an employee and tests performed at the request of an employer. Nor does it distinguish between screening tests and surveillance tests. It also confuses the results by combining employees and potential employees. The legal implications of using these two types of test subjects may differ significantly. Companies may refuse to respond for fear that their responses may be misinterpreted. Many companies lack facilities for testing and therefore are likely to contract with independent laboratories for any testing they perform. There may be doubt as to whether such outside testing should generate a "yes" response.

Question 2: The comments to question 1 apply also to this question. Moreover, a single test performed at some point in the past for any reason would lead to an affirmative response and thereby distort the results.

Question 3: This question contains a severe affirmative bias. An objective questionnaire would not limit the recipient to the three choices: "definitely yes," "possibly yes" and "no." One who cannot answer definitely yes or no is forced into the "possibly yes" response. His response could equally be "possibly no" or, as is more likely, "no anticipation."

Question 4: The comments on question 1 are also applicable here.

Question 5: The comments on questions 1 and 2 are also applicable here.

Question 6: The comments on question 3 are also applicable here.

Question 7: This question fails to differentiate among several different tests. Many of the tests referred to are not necessarily performed for the endpoints listed. For example, a test for respiratory disease or contact dermatitis may have been performed for purposes unrelated to a screen for immune system markers. It would be more useful to ask whether tests have been conducted for specified purposes, and not whether workers have been screened for certain conditions without regard for the purpose of the test. In addition, as with questions 1, 2, 4 and 5, this question fails to differentiate between tests of a single employee and tests of many employees or between tests requested by employees and tests requested by employers or between screening tests pre-employment and tests on employees. Although the question refers only to screening, it is unclear whether surveillance tests (which may be for screening purposes) are to be excluded.

Question 8: The format of this question is highly impractical. Each of the "conditions" referred to in the subsections A through D includes several possible tests. For some such tests the answers to question 8 may be "yes"; for others, "no". The questions themselves are quite ambigious. The parentheticals serve to increase, rather than descrease, the confusion. Subpart (b), for example, refers to "unusual situations such as a chemical spill." A recipient might wonder whether a test performed on a single occasion at the request of an employee calls for a positive response, and whether, if it does, you will attribute all such responses to situations comparable to your "chemical spill" illustration.

Question 9: The comment to question 8 regarding the possibility of multiple responses is equally applicable. In addition, responses to questions 9 (b) and (c) might be interpreted as suggesting unlawful discrimination. It is highly unlikely that companies would respond in the affirmative to such questions.

Question 10: This question attempts to obtain a simple answer to what is often a complicated issue. It assumes that a single individual makes such a decision--an assumption which we believe is unwarranted in most large companies. Most decisions of this sort are likely to be made by a team, including medical, legal and other personnel, with several layers of review.

Question 11: This question also will produce questionable results because of its failure to distinguish between tests of a single employee performed at the request of the employee and tests of many employees at the employer's request. The question also gives the recipient an unfortunate choice of "factors." For example, "strength of the association between chemical exposure and illness" suggests that such an association is known. The test may be part of a research effort to determine whether an association may exist. Where such matters of chronic health effects are unclear, you may generate more useful information if you offer recipients the following language: "data suggesting a possible association. . . ." Answer E also contains an unfortunate choice of words. The relationship between employees and management is not necessarily one of "pressure." Such relationship often includes cooperative efforts. Your draft suggests otherwise. The question also will bias the survey results. To be objective, the question should include both decisions to implement a test program and decisions not to implement such a program. A single company may have decided to conduct one test or to implement a test program for one reason and not to implement another test program for another reason. Yet your questionnaire will record all companies that ever conducted a single test in one category and all companies that never tested in another. We question the utility of such a composite.

Question 12: While selection criteria information may be useful when related to a specific test selected, your questionnaire consolidates in a single answer the criteria for all testing ever conducted. Thus, in one case a company might have employed one set of criteria to select one test for one purpose, while in another situation the same company may have employed different criteria for another test with a different purpose. Unless you can associate the response to this question with the type and purpose of testing, you cannot attribute any significance to the results.

Question 13: This question is a non sequitur. One does not "screen workers for exposure to chemicals by" the various genetic endpoints or mutagenicity assays referred to in A through D. In other words, your question does not refer to methods of screening workers for exposure to chemicals. It refers to two genetic endpoints (A and B) and to two general descriptions of tests (C and D), none of which are used to "screen workers for exposure to chemicals." If the question is revised to ask simply whether the recipient company ever screened workers for chromosomal aberrations, sister chromatid exchange, DNA damage or enzyme effect, it again fails to differentiate between a single test and a large test program or between employee-requested tests and employer-requested tests.

Question 14: The comments on question 8 are also applicable here. With regard to some tests, a company might have tested routinely; with regard to others, it might not have tested routinely. The "yes" and "no" format is impractical. As noted above, the subparts of this question tend to be misleading.

Question 15: The comments on question 9 are also applicable here.

Question 16: The comments on question 10 are also applicable here.

Question 17: The comments on question 11 are also applicable here.

Question 18: The comments on question 12 are also applicable here.

Question 19: This question is ambiguously worded. If you mean to ask about testing to determine whether there is any relationship between chromosomal abnormalities and exposure to workplace chemicals, you might reword the question. Recipients may well be confused by the phrase "genetic predisposition to workplace chemicals." We are not aware that the phrase has a commonly understood meaning. We also wonder whether this composite question, when properly rephrased, is appropriate for a "yes" or "no" response.

Question 20: This question is totally inappropriate for your survey. First, it will generate a misleading and unscientific "statistic." It is obviously not the function of this survey to determine the proportion of occupational diseases, if any, that are "attributable" or "mainly due" to workplace chemicals. In our discussions, you have suggested that a subjective opinion is requested and that the results will be reported as such. However, the refinement with which the answer must be given contradicts the subjective nature of the question. We know of no way validly to aggregate speculations based on a wide variety of undisclosed foundations or biases. The question assumes that the recipient will have a basis for forming an opinion and that that opinion will have value. Yet you have no method of control designed to ensure that the person answering the questionnaire had valid data and is scientifically qualified to express such an opinion. Second, the question is biased. The lowest answer a recipient can give is "5% or less." There is no "zero" or "no opinion" option. Third, you have suggested that this question will help you determine whether there is a relationship between a company's decision to test and a company's opinion on the causes of occupational diseases. If that is your rationale, questions 11 and 17 appear much better suited to generating the information you need. In any event, we doubt that any company has formulated a company policy or opinion that could be used in responding to question 20. Opinions on the proper role of screening for hypersensitive workers could be obtained in a survey of properly qualified and informed respondendents.

Question 21: The comments to question 20 are also applicable here. This question would more properly be addressed in a scientific symposium which began with a state-of-the-art discussion of the relationship, if any, between chromosomal aberrations and occupational disease. The next issue to be addressed would be "cause and effect" relationships. "Attributable" is a very inexact word which may result in numbers in excess of 100 percent when all "attributing" factors are listed.

Question 22: Because of its failure to distinguish among types of tests, this question is of limited utility. In addition, the possible responses include activities that might be interpreted to relate to unlawful discrimination. It is unlikely that companies would respond affirmatively to such suggestions.

Question 23: Comparing this question to questions 11 and 17 suggests a bias in favor of finding specific reasons for decisions to test and against finding specific reasons for decisions not to test. Both questions should be asked from an equal footing. Moreover, as indicated above, companies that have conducted some testing may also have decided not to conduct other testing. You have eliminated the latter decisions from your survey.

Question 24: The comments to question 23 are also applicable here.

Question 25: This question is not appropriate for a survey in which confidentiality is expected to be important. It would seem more appropriate to ask the question in a separate mailing. Moreover, without knowing the exact subject matter of hearings, it is unlikely that companies will respond affirmatively.

Question 26: As noted above, identifying information can be expected to have a significant negative impact on the response rate.

Question 27: It is unlikely that a significant number of companies that decide not to respond to the questionnaire will respond to this question.

If you have any questions or would like to discuss these matters further, please do not hesitate to call.

Sincerely yours,

R. Bruce Dickson

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JOHN D. DINGELL, MICH.
LARRY WINN, JR., KANS.
CLARENCE E. MILLER, OHIO
COOPER EVANS, IOWA
JOHN H. GIBBONS

Congress of the United States
OFFICE OF TECHNOLOGY ASSESSMENT
WASHINGTON, D.C. 20510

JOHN H. GIBBONS
DIRECTOR

March 12, 1982

Mr. R. Bruce Dickson
Cleary, Gottlieb, Steen & Hamilton
1250 Connecticut Ave., N.W.
Washington, D.C. 20036

Dear Mr. Dickson:

Thank you for your extremely helpful letter of February 12, 1982 to my colleague, Dr. Ann Rose, regarding the draft questionnaire on occupational genetic testing. The comments that you relayed were carefully considered by the project staff and the person who is overseeing the survey for our contractor, the National Opinion Research Center. As a result of these and other comments, many revisions have been made in the questionnaire. In fact, substantial staff time has been spent in finalizing the questionnaire and the survey procedures. As a result, I have not responded to your letter as quickly as I would have liked. Please excuse the delay.

I would like to respond specifically to one comment in your letter. You stated that the "tone of the questionnaire suggests that the results will be used to indict genetic testing as a means to discriminate in hiring and in job placement." We regret that your reviewers inferred this from the document, since its purpose will be simply to gather information fully and objectively. As you probably know, the Office of Technology Assessment is a nonpartisan organization designed to provide Congress with an objective and balanced analysis of issues and policy options relating to science and technology. The staff of this project takes that duty very seriously and brings no preconceived notions to either the survey or the assessment as a whole. As you know, the questionnaire was a draft document, which the staff expected to revise. In the revision process, we have attempted to eliminate any language that respondents might find objectionable, clarify ambiguous questions, improve the format, and provide respondents with an opportunity explain any of their answers.

Once again, thank you for your comments. I hope that members of the American Industrial Health Council will continue to work with us on this project by commenting upon staff and contractor work product.

Sincerely,

Geoffrey M. Karny

Geoffrey M. Karny
Project Director

**AIHC** AMERICAN INDUSTRIAL HEALTH COUNCIL, INC.
1075 CENTRAL PARK AVENUE • SCARSDALE, NEW YORK 10583 • (914) 725-1492

March 11, 1982

TO: DESIGNATED CONTACTS
EXECUTIVE COMMITTEE
LEGAL COMMITTEE
SCIENTIFIC COMMITTEE
MUTAGENICITY SUBCOMMITTEE
QUANTITATIVE RISK ASSESSMENT SUBCOMMITTEE
SCIENCE POLICY TASK FORCE
OSHA TASK FORCE
EPA TASK FORCE

OTA WORKPLACE SURVEY

OF CYTOGENETIC TESTING

Gentlemen:

Attached is the revised OTA survey form that was sent to a small group of companies in a pretest of the workplace survey. Certain editorial changes have been made in the original draft, and OTA will not ask for identifying information. The draft does contain what appears to be an identification number in the upper right hand corner, however. The questionnaire retains most of the objectionable features of the original draft, as discussed in our letter of February 12, 1982.

We are informed that the survey will be an item of discussion at an OTA Occupational Genetic Testing Advisory Panel meeting on March 19, 1982. Also discussed will be the four draft contractor reports on workplace testing.

Sincerely,

R. Bruce Dickson

R. Bruce Dickson

Attachment

FOR REVIEW ONLY —
NOT FOR REFERENCE, QUOTATION,
OR REPRODUCTION

## WORKPLACE SURVEY

### INSTRUCTIONS FOR COMPLETING THE QUESTIONNAIRE

The questions concern biochemical genetic and/or cytogenetic testing planned, conducted, contracted or arranged for by your company on one or more employees or potential employees. By biochemical genetic tests we mean tests which screen for particular heterozygous or homozygous genetic traits listed in question 7, and not standard blood chemistry tests. Cytogenetic tests are intended to detect chromosomal aberrations or sister chromatid exchanges.

Do not sign the questionnaire or record any identifying information. Answers should include any instances of testing in your corporation.

---

1. Is your company currently conducting biochemical genetic testing of employees or potential employees? Yes ☐ No ☐

2. Has your company conducted any biochemical genetic testing of employees or potential employees since 1970? Yes ☐ No ☐

3. Does your company anticipate conducting biochemical genetic testing in the next five years? Yes ☐ No ☐ Possibly ☐

4. Is your company currently conducting cytogenetic testing of employees or potential employees? Yes ☐ No ☐

5. Has your company conducted any cytogenetic testing of employees or potential employees since 1970? Yes ☐ No ☐

6. Does your company anticipate conducting cytogenetic testing during the next five years? Yes ☐ No ☐ Possibly ☐

IF CYTOGENETIC TESTING HAS EVER BEEN DONE, PLEASE ANSWER QUESTIONS 12-16. IF NOT, PLEASE SKIP TO Q. 18.

12. Has your company tested workers for exposure to chemicals by looking for . . .

| | Yes | No |
|---|---|---|
| A. chromosomal aberrations | ☐ | ☐ |
| B. sister chromatid exchanges (SCE) | ☐ | ☐ |
| C. mutations by assaying the DNA | ☐ | ☐ |
| D. mutations by assaying the enzymes | ☐ | ☐ |
| E. something else? What? ______________ | ☐ | ☐ |

ENTER BELOW NAME OF EACH SPECIFIC CONDITION TESTED (e.g., SCE). ANSWER QUESTIONS 13 & 14 FOR EACH. IF MORE THAN 4 CONDITIONS, ANSWER ON ADDITIONAL SHEET OF PAPER.

| ENTER SPECIFIC CONDITION NAME HERE→ | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Yes | No | Yes | No | Yes | No | Yes | No |
| 13. Was testing done . . .<br>a) routinely (e.g., yearly) or during regular specified circumstances? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| b) for research purposes (e.g., hypothesis testing)? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| c) for any other reasons? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| 14. Was the decision to test ever based on an employee's . . .<br>a) job category? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| b) sex? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| c) ethnic or racial background? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

15. What factors have been considered in decisions to implement any cytogenetic testing programs?

A. Cost benefit analysis ☐
B. Data suggesting a possible association between chemical exposure and illness in animal studies ☐
C. Data suggesting a possible association between chemical exposure and illness in epidemiologic studies ☐
D. Legal consequences of failure to test ☐
E. Union/employee initiative ☐
F. Something else. What? ______________ ☐

16. What criteria were employed in the choice of a specific test?

A. Predictive value of the test ☐
B. Sensitivity of the test ☐
C. Specificity of the test ☐
D. Scientific consensus ☐
E. Cost of the test ☐
F. Something else. What? ☐ ______________

NORC/4394 3/82

## WORKPLACE SURVEY

### INSTRUCTIONS FOR COMPLETING THE QUESTIONNAIRE

The questions concern biochemical genetic and/or cytogenetic testing that may have been conducted by your company on one or more employees or potential employees. By conduct we mean do, contract for, or arrange for. By biochemical genetic tests we mean tests which screen healthy, asymptomatic individuals for the particular genetic traits listed in question 7, and not standard blood chemistry tests or tests used solely for diagnosis. Cytogenetic tests are intended to detect chromosomal aberrations or sister chromatid exchanges.

Do not sign the questionnaire or record any identifying information on it. Answers should include any instances of testing in your corporation.

Please return the questionnaire to NORC before April 12.

---

1. Is your company currently conducting biochemical genetic testing of employees or potential employees? Yes No

---

2. Has your company conducted any biochemical genetic testing of employees or potential employees in the past twelve years? Yes No

---

3. Does your company anticipate conducting biochemical genetic testing in the next five years? Yes No Possibly

---

4. Is your company currently conducting cytogenetic testing of employees or potential employees? Yes No

---

5. Has your company conducted any cytogenetic testing of employees or potential employees in the past twelve years? Yes No

---

6. Does your company anticipate conducting cytogenetic testing during the next five years? Yes No Possibly

---

IF YOUR COMPANY NEVER HAS DONE EITHER BIOCHEMICAL GENETIC OR CYTOGENETIC TESTING, SKIP TO QUESTION 18.

7. Has your company tested workers for . . .
   A. any red blood cell and serum disorders, including sickle cell trait, glucose-6-phosphate dehydrogenase deficiency (G-6-PD), methemoglobin reductase deficiency, serum alpha-1-antitrypsin deficiency (SAT), alpha and beta thalassemia?

   B. any liver detoxification systems, including aryl hydrocarbon hydroxylase inducibility (AHH), slow vs fast acetylation?

   C. any immune system markers, including allergic respiratory disease, contact dermatitis, histocompatibility markers (HLA)?

   D. any heterozygous chromosomal instabilities, including Bloom syndrome, Fanconi syndrome, ataxia-telangiectasia, xeroderma pigmentosum?

ENTER BELOW NAME OF EACH SPECIFIC CONDITION TESTED FOR (e.g., G-6-PD). ANSWER QUESTIONS 8 & 9 FOR EACH. IF MORE THAN CONDITIONS, RECORD ON ADDITIONAL SHEET OF PAPER.

| ENTER SPECIFIC CONDITION NAME HERE---> | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Yes | No | Yes | No | Yes | No | Yes | No |
| 8. Was testing done . . .<br>a) routinely (e.g., yearly) or during regular specified circumstances? | | | | | | | | |
| b) for research purposes (e.g., hypothesis testing)? | | | | | | | | |
| c) for any other reasons? | | | | | | | | |
| 9. Was testing to detect increased risk of disease ever based on an employee's . . .<br>a) job category? | | | | | | | | |
| b) sex? | | | | | | | | |
| c) ethnic or racial background? | | | | | | | | |

10. What factors have been considered in decisions to implement any biochemical genetic testing program?

A. Cost benefit analysis

B. Data suggesting a possible association between chemical exposure and illness in animal studies

C. Data suggesting a possible association between chemical exposure and illness in epidemiologic studies

D. Legal consequences of failure to test

E. Union/employee initiative

F. Something else. What? ____________

11. What criteria were employed in the choice of a specific test?

A. Predictive value of the test

B. Sensitivity of the test

C. Specificity of the test

D. Scientific consensus

E. Cost of the test

F. Something else. What?

____________

[illegible] 12-16 — IF NOT, PLEASE SKIP TO Q. 17.

12. Was [illegible] exposure to chemicals to look for . . .

| | Yes | No |
|---|---|---|
| A. chromosomal aberrations | ☐ | ☐ |
| B. sister chromatid exchanges (SCE) | ☐ | ☐ |
| C. mutations by assaying the DNA | ☐ | ☐ |
| D. mutations by assaying the enzymes | ☐ | ☐ |
| E. something else? What? ________ | ☐ | ☐ |

ENTER BELOW NAME OF EACH SPECIFIC CONDITION TESTED FOR (e.g., SCE). ANSWER QUESTIONS 13 & 14 FOR EACH. IF MORE CONDITIONS, RECORD ON ADDITIONAL SHEET OF PAPER.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| ENTER SPECIFIC CONDITION NAME HERE----> | | | | | | | |
| | Yes | No | Yes | No | Yes | No | Yes |
| 13. Was testing done . . .<br>a) routinely (e.g., yearly) or during regular specified circumstances? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| b) for research purposes (e.g., hypothesis testing)? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| c) for any other reasons? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| 14. Was testing to detect increased risk of disease ever based on an employee's. . .<br>a) job category? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| b) sex? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| c) ethnic or racial background? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

15. What factors have been considered in decisions to implement any cytogenetic testing programs?

A. Cost benefit analysis ☐
B. Data suggesting a possible association between chemical exposure and illness in animal studies ☐
C. Data suggesting a possible association between chemical exposure and illness in epidemiologic studies ☐
D. Legal consequences of failure to test ☐
E. Union/employee initiative ☐
F. Something else. What? ________ ☐

16. What criteria were employed in the choice of a specific test?

A. Predictive value of the test ☐
B. Sensitivity of the test ☐
C. Specificity of the test ☐
D. Scientific consensus
E. Cost of the test
F. Something else. What? ________

17. Which actions has your company ever taken as a result of biochemical genetic or cytogeneti testing?

A. Informed employee of a potential problem ☐

B. Suggested employee seek job elsewhere ☐

C.* Placed an employee or transferred an employee to a different job in the company ☐

D. Implemented engineering controls ☐

E. Recommended personal protection devices ☐

F. Implemented a research program ☐

G. Discontinued a product or changed materials in a product ☐

H. Some other action. What? ☐

____________________________

---

18. Has your company ever conducted any testing on whole animals or their cultured cells for . . .

| | Yes | No |
|---|---|---|
| A. chromosomal aberrations or sister chromatid exchanges as a result of exposure to workplace chemicals? | | |
| B. genetic predisposition to harmful effects from exposure to workplace chemicals? | | |

---

19. What is the major industrial classification of your company (such as chemicals, food or textiles)?

---

20. Please use this space for your comments, if any, about these questions.

---

Thank you for completing this questionnaire. The information you have provided will be hel strict confidence. Data will be made available to Congress in statistical form only.

Mr. **Gore**. I mean, it just is unseemly, it seems to me, for an industry group like this to make it more difficult for OTA to accomplish results it is trying to accomplish at our request.

I recognize counsel for the minority.

Mr. **Clement**. Mr. Chairman, would you consider at that point also including in the record the draft questionnaire form that the memo comments on?

Mr. **Gore**. This comments on the final draft, and of course we will include that in the record. In fact, it is already in the record.

Dr. **McCarville**. Mr. Chairman, may I add one other comment?

Mr. **Gore**. Yes, please do, because I am a little troubled by this.

Dr. **McCarville**. I do not know what the sensitivity of the various companies who received that questionnaire might have been. I know for a fact that not all companies were concerned about anonymity. As a matter of fact, I am aware that a number of companies openly wrote cover memos attached to their responses.

Mr. **Gore**. Yes. Yes, but you see my point: OTA is trying to get this information to help the Congress wrestle with these extremely difficult issues. I mean, these are tough. They are right on the frontier and they are going to be very, very difficult. OTA goes to great length to prepare this questionnaire, to send it out to the Fortune 500. If you were conducting such a study and hoping for a good response, I doubt that you would be interested in having a trade group send out the draft ahead of time telling them, all the potential respondents, that it is objectionable and it looks like they are going to secretly find out the identity of everybody responding.

Dr. **McCarville**. Well, Mr. Chairman, I can assure you that was not our intent.

Mr. **Gore**. Particularly since the trade group had been afforded the courtesy of commenting on the study ahead of time and offering suggestions on how to improve it.

Dr. **McCarville**. Well, I can assure you it was not our intent to dissuade anyone from completing the questionnaire and apparently from the 65-percent response, that certainly was not the outcome.

Mr. **Gore**. Well, if such an effort was made it was just unsuccessful.

Dr. **McCarville**. It was not made, I can assure you.

Mr. **Gore**. All right.

What were your remaining objections to the survey?

Dr. **McCarville**. Well, there were several. Among them, as I said, we felt there was not a clear enough definition of exactly what OTA was looking for in the biochemical versus the cytogenetic area.

No. 2, frankly, while I heard the group who spoke to you this morning saying that they sent it to the chief executive officers, we felt that was probably not the place to go because we were very concerned that in many cases it would get to some administrative assistant and be filled out and either return bad information or perhaps no information; that in fact, had they wanted to get the attention of the chief executive officer, it might have been better addressed to the chief executive officer with the chief medical officer as a coaddressee.

Not all of the companies in the Fortune 500 or, for that matter, in U.S. industry have such clean lines of communication that you can be assured of getting it to the person most qualified to answer.

Mr. **Gore**. Well, could you supply the February 12 letter to us? We would like to look at that, for consideration of putting that in the record and affording OTA the opportunty to provide a response.

Dr. **McCarville**. Certainly.

Mr. **Gore**. OK? Thank you very much. We are going to move on to our final panel. I appreciate it very much.

Our final panel is made up of Robert Barnard, a lawyer with Cleary, Gottlieb, Steen & Hamilton; Professor Mark Rothstein of the College of Law at the University of West Virginia; and James English, a lawyer with the United Steelworkers of America.

Gentlemen, would you stand and raise your right hands, please? Do you solemnly swear that the testimony you are about to give will be the truth, the whole truth, and nothing but the truth, so help you God?

Mr. **Barnard**. I do.

Mr. **Rothstein**. I do.

Mr. **English**. I do.

Mr. **Gore**. Thank you very much. Without objection, the prepared statements of all three participants will be put into the record in full at this point. Mr. Barnard, we would like to begin with you. We appreciate your presence here and welcome you. Please proceed as you see fit.

## STATEMENT OF ROBERT BARNARD, ESQ., CLEARY, GOTTLIEB, STEEN & HAMILTON, WASHINGTON, D.C.

Mr. **Barnard**. Thank you very much, Mr. Chairman.

As you noted, I am a partner in the Washington law firm of Cleary, Gottlieb, Steen & Hamilton. I am here today to discuss the legal issues that arise in the use of the workplace of diagnostic screening tests and medical technologies.

In order that the committee will know where I am coming from I should say that I am counsel to the American Industrial Health Council, the Synthetic Organic Chemical Manufacturers, and other associations but I am not here appearing on their behalf today. I am here to discuss legal issues and it is in that capacity that I am testifying; I am not representing these other associations but I wanted you to know whom I represented.

Last fall I was invited to a symposium on "The Protection of the Sensitive Worker," organized by the American Conference of Government Industrial Hygienists and the Arizona Center for Occupational Safety and Health. In the paper that I presented at that conference I discussed the legal issues involved in various medical/scientific techniques to screen and protect workers and to protect the fetus. There have been no important developments substantively since I prepared that paper—a couple of cases are still pending on appeal—and with the chairman's permission, I would like to put that paper in the record in lieu of prepared testimony.

Mr. **Gore**. We have received that and, without objection, we will put that in the record.

Mr. **Barnard**. That paper will appear in the proceedings of the ACGIH and the Arizona COSH, so that the paper will be published in due course in slightly modified form because of publication format.

Now with the committee's permission, I would like to summarize briefly the conclusions, legal conclusions that were developed from the discussion of the regulation and the cases in the paper that has just been filed.

First, the statutes: There are two relevant Federal statutes, the Occupational Safety and Health Act which directs OSHA to develop standards for toxic substances to assure that "no employee will suffer material impairment of health or functional capacity." The OSH Act also imposes a general duty on employers to furnish to each employee a workplace free of recognized hazards.

Title 7 of the Civil Rights Act forbids discrimination in employment on the grounds of race, color, religion, sex, or national origin. There are other statutes, Mr. Chairman, that are relevant but those two have been the center of the decisions on regulations and the cases that have been pending in the courts.

I would like next to discuss what is commonly called in many circles a BFOQ, that is, a bona fide occupational qualification. I think the cases establish, and it is generally accepted that an employer can establish criteria for employment and promotion which fairly measure performance on the job. A truckdriver must be able to see; you cannot hire a blind man as a truckdriver. Persons with special sensitivities may be unsuitable for certain jobs. A man with acrophobia—fear of heights—may not be a good steelworker on bridges. A person with the genetic sensitivity to ultra violet rays, the condition known as xeroderma pigmentosa, may not be suitable for outside work because any exposure to those rays will induce cancer in the individual.

These qualifications are commonly called BFOQ's, bona fide occupational qualifications. The legal issues arise from the tension on one hand between the legitimate interest of the employer in establishing BFOQ and the scientific validity of tests and data used in connection with those qualifications, and on the other hand, the legal requirements of the OSH Act and title 7.

It was very interesting this morning to hear the report, the preliminary report of OTA. As the chairman has brought out in questioning the witnesses earlier, there are two kinds of screening, biochemical screening—which has been known for some time and which has a reasonably established scientific base—and cytogenetic screening, which is a relatively new development and has a reasonable data base only in connection with exposure to radiation.

It will not be until the whole OTA report is available that we will be able to see whether cytogenetic screening or biochemical screening are being used in connection with employment decisions and who is using them. These testing methods, particularly the newer methods of cytogenetics, have not to my knowledge figured in any court decisions, and so this committee's discussion of the legal issues will have to depend on more general principles. The discussion of the tests is at the frontier of knowledge, although I do not think it is at the frontier so far as legal issues are concerned.

Let me see if I can summarize what I understand to be the legal issues involved in the use of testing, whether it is biochemical, cytogenetic, or medical. These are the conclusions that I think come out of the decisions under the OSH Act and title 7. There are two cases pending on appeal; when they are decided, maybe we can enlarge what I am about to say.

As of now, I think the cases support the conclusion that BFOQ's, which have the effect of excluding certain individuals from the workplace, are legal and nondiscriminatory if soundly based in science or medicine. Let me emphasize two aspects of this conclusion because I think they are the foundation of the basic legal principle.

First, the occupational qualification must be bona fide and reasonably related to performance on the job. BFOQ can be health related; the purpose of the BFOQ can be to avoid potential harm to the worker on the job. BFOQ may justify dismissal if an employer can demonstrate that because of the employee's particular sensitivity, his or her health cannot be reasonably protected on the job—I point out, reasonably protected.

In two cases OSHA has limited the right to dismiss. In the cotton dust case there is a medical transfer provision requiring transfer to another job if it is available, and in the lead standard case there is a so-called medical removal provision requiring removal and maintenance for 18 months, whether or not there is a job.

A soundly based BFOQ policy can validly provide protection to the fetus as a separate entity, separate from the mother, by excluding women of childbearing age from certain jobs which involve exposures which may harm the fetus.

The second aspect of the legal principle is that the medical or scientific tests which are used to identify qualifications or, in the context of this hearing, are used to identify disqualifications—sensitivities, limitations, or other characteristics which make a person unsuitable for a job—must be valid scientifically. The tests used and the data which are relied upon must be scientifically and reasonably applied and must be sound scientifically.

How do I relate these principles to the testing systems which are discussed in the OTA report? If an employer decides to establish as a BFOQ a characteristic which is identified by, or measured by, one of the tests surveyed by the OTA, the employer will have to establish initially that the characteristic is reasonably related to performance on the job, including avoidance of health risks to the individual from the job conditions. There must be some valid, employment-related end point in order to establish a BFOQ.

The tests and data relied upon must be scientifically sound. For a lawyer the question is: Would a court conclude on the basis of all of the facts that the test and test data are scientifically valid and reasonably applied? Unfortunately, the summary of the OTA report does not give enough information so that you can judge the validility of tests or test data in any particular context. These issues can be judged legally only on a case-by-case basis with a full evalutaion of the particular facts in the particular case.

I think, Mr. Chairman, that is really all I would like to say at the outset and I would prefer then to leave the rest to questions.

[The prepared statement of Mr. Bernard follows:]

June 22, 1981

Hearings Before the
Subcommittee on Investigations and Oversight
Statement of Robert C. Barnard

My name is Robert C. Barnard. I am a partner in the Washington office of the law firm Cleary, Gottlieb, Steen & Hamilton.

I am pleased, Mr. Chairman, to be invited to participate in the panel to discuss legal issues that may arise in connection with the use in the workplace of diagnostic screening tests and medical technologies.

In order that the Committee will understand where I am "coming from", I would like to say at the outset that in my practice I represent, among others, the American Industrial Health Council (a broad based industrial organization with some 120 members) and the Synthetic Organic Chemical Manufacturers Association (an association of the producers of synthetic organic chemicals). However, I am not here today representing those clients. I was invited to appear as a lawyer to discuss the legal issues involved in the use of medical/scientific screening techniques in the work place and it is in that capacity that I am addressing the legal issues.

Last Fall I delivered a paper at a symposium on The Protection of the Sensitive Worker, co-sponsored by the American Conference of Governmental Industrial Hygienists and the Arizona Center for Occupational Safety and Health. My paper discussed the legal issues involved in use of various medical/scientific techniques to screen or protect workers or the fetus. There have been no important substantive legal developments since I wrote my paper, and, with the Chairman's permission, may I submit the paper in lieu of prepared testimony.

I would now like, with the Committee's permission, to summarize briefly my conclusions based on the discussion of the cases and regulations in my paper.

## The Statutes

There are two relevant federal statutes:

- The Occupational Safety and Health Statute directs OSHA to develop standards for toxic substances to assure that "no employee will suffer material impairment of health or functional capacity..."

  In addition the OSH Act imposes a "general duty" on employers to furnish "to each employee" a workplace "free from recognized hazards that are causing or likely to cause death or serious physical harm" to the employee.

- Title VII of the Civil Rights Act forbids discrimination in employment on grounds of race, color, religion, sex or national origin.

- There are other statutes administered by EPA or NRC which relate to the protection of workers and the special problems of protecting the separate entities: working women and fetuses. However, the main legal developments have been under the OSH Act and Title VII and I will focus on them.

## BFOQ

It is I believe generally accepted that an employer can establish criteria for employment and promotion which fairly measure performance on the job. A truck driver must be able to see; persons with special sensitivities or limitations may be unsuitable for certain jobs - a man with acrophobia (fear of heights) may not be suitable for a bridgeworkers job and a person with the genetic hypersensitivity to ultra violet rays of the sun (xeroderma pigmentosa) may not be suitable for outdoor farm work. These are commonly referred to as Bona Fide Occupational Qualifications - BFOQ for short.

The legal issues arise from the tension between, on one hand, the legitimate interest of the employer in establishing BFOQ and the scientific validity of tests and data used and, on the other hand, the legal requirements of the OSH Act and Title VII.

## Report of the Office of Technology Assessment

The OTA Report which was briefly summarized earlier deals with testing methodologies. Some biochemical screening tests covered by the Report have been known for some time. Cytogenetic testing is a relatively new development with a reasonable data base only for radiation.

When the whole OTA Report is available, it may tell which of these testing methods are being used for employment decisions and, if so, how they are being used. These testing methods, and particularly the newer discipline of cytogenetics, have not yet figured in court decisions so this Committee's consideration of the legal issues is at the frontier with little specific experience to rely on.

## Summary of Legal Principles

I would like to try to state in summary form some conclusions that grow out of the regulations and court decisions interpreting the OSH Act and Title VII. There are two cases pending on appeal, both involving the validity of employer actions to protect the fetus. When those cases are finally decided, we may have new insights. As of now, I think the cases support the following conclusions:

> BFOQ which have the effect of excluding certain individuals from the workplace are legal and non discriminatory if soundly based in medicine or science.
>
> Let me emphasize the two aspects of this conclusion because I think they are the foundation of the basic legal principles.
>
> First. The occupational qualifications must be bona fide and reasonably related to performance on the job. BFOQ can be health related; the purpose of the BFPQ can be to avoid potential harm to the worker on the job. BFOQ may justify dismissal if an employer can demonstrate that because of the employee's particular sensitivity, his or her health cannot reasonably be protected on the job. In two cases OSHA has limited the right to dismiss: the Cotton Dust standard contains a medical transfer provision

requiring transfer to another job if available and the Lead standard contains a medical removal provision requiring that a worker be maintained whether or not a job is available for a period up to 18 months.

A soundly based BFOQ policy can validly provide protection to the fetus as an entity separate from the mother by excluding women of childbearing age from certain jobs which involve exposures which may harm the fetus.

Second. The medical or scientific tests which are used to identify qualifications or, in the context of this hearing, the disqualification - sensitivities, limitations or other characteristics which make a person unsuitable for a job - must be valid scientifically. The tests used and the data which are relied upon must be sound scientifically and reasonably applied.

How do these principles relate to the testing systems which are discussed in the OTA Report:

If an employer decides to establish as a BFOQ a characteristic which is identified by or measured by one of the tests surveyed by the OTA, the employer will have to establish initially that the characteristic is reasonably related to performance on the job including avoidance of health risks to the person from the job conditions. There must be some valid employment related end point in order to establish a BFOQ.

The tests and data relied upon must be scientifically sound. For a lawyer, the question is: would a court conclude on the basis of all the facts that the test and test data are scientifically valid and reasonably applied.

The summary of the OTA Report does not provide enough information to judge the validity of the test or test data in any particular context. Those issues can be judged legally only on a case-by-case basis with a full evaluation of the particular facts.

Mr. GORE. Good. Thank you very much. That is excellent testimony and very helpful.

Professor Rothstein, we have a vote on the floor and rather than interrupt you in the middle of your testimony, I think it would be best to break now. It will not take more than 7 or 8 minutes. Then we will come back and hear from you at that point.

[Recess taken.]

Mr. GORE. The subcommittee will come back to order.

Professor Rothstein, would you proceed?

## STATEMENT OF PROF. MARK ROTHSTEIN, COLLEGE OF LAW, WEST VIRGINIA UNIVERSITY

Mr. ROTHSTEIN. Thank you, Mr. Chairman.

In the written statement I submitted to the subcommittee, I summarized the main legal issues raised by the use of biochemical genetic and cytogenetic screening in the workplace. In my remarks today, I would like to address the problem from a slightly different perspective. First I will assume that the screening procedures have a low predictive value and, second, I will assume that they have a high predictive value.

If the particular form of screening has a low predictive value, it could be either that the test is inaccurate in measuring the existence of a particular trait or invalid because there is little correlation between the presence of the trait and an increased risk of occupational illness. When the use of a test with a low predictive value results in the adverse treatment of an applicant or employee, the result is certainly unfair in the everyday sense. The remaining questions are: Should the law remedy this unfairness and, if so, how should this be done?

Employees working without a contract of employment may be discharged by their employer for any reason that does not violate a specific statutory prohibition or some public policy. The public policy exception to the so-called at will doctrine has never been held to extend to unfair dismissals based on the use of medical testing with low predictive value. A similar analysis, of course, would apply to the refusal to hire.

Therefore, the use of even low predictive value tests would not give rise to any common-law action by the individual. No Federal law currently provides adequate protection in this situation, either. OSHA regulates the physical conditions in the work environment but not employment rights. Some OSHA health standard detail what medical procedures must be performed but they do not indicate what procedures may not be performed, and except for the cotton dust and lead standards, they do not proscribe any personnel actions that may be taken as a result of a medical determination.

If the Secretary of Labor were to promulgate sweeping standards that protected the employment rights or job security of employees, it is quite likely that the standards would be struck down by the courts as being outside of OSHA's statutory authority. As the Supreme Court recent stated in the cotton dust case, "The act in no way authorizes OSHA to repair unfairness to employees that is unrelated to achievement of health and safety goals."

The Rehabilitation Act of 1973 prohibits discrimination in employment by employers who are Government contractors or recipients of Federal financial assistance against otherwise qualified handicapped individuals. The statute defines handicapped individual very broadly, to include any person who (a) has a physical or mental impairment which substantially limits one or more of such person's major life activities, (b) has a record of such an impairment, or (c) is regarded as having such an impairment. It is not clear whether these individuals who have a heightened future risk of illness are handicapped and therefore covered by the law or whether they are otherwise qualified. The coverage and available remedies under the Rehabiliation Act are also inadequate for these types of cases.

Finally, title 7 of the Civil Rights Act of 1964 which prohibits discrimination on the basis of race, color, religion, sex, or national origin, may be used where there is a disparate impact caused by the test, but this would only occur in some forms of biochemical genetic screening such as sickle-cell trait and not in cytogenetic screening. Moreover, certain title 7 defenses could justify the use of these procedures.

At the State level there has been some recent activity but the protections are still quite limited. New Jersey prohibits employment discrimination based on an individual's atypical hereditary cellular or blood traits, which is defined to include sickle-cell trait, hemoglobin-C trait, thalessemia trait, tay-sachs trait, or cystic fibrosis trait. Florida and North Carolina prohibit discrimination in employment based on sickle-cell trait. These are the only State laws in this area. It is apparent that new legislation is needed if the unfairness of discrimination based on testing with low predictive values is to be remedied.

The second assumption I would like to make is that the screening procedures have a high predictive value. At first glance it would seem that there are no problems here, as long as the predictive values are high. Nevertheless, there are quite serious potential problems. If the use of genetic screening becomes common, it is foreseeable that the potential work force will be screened into at least two classes of individuals. One group would contain super healthy, disease-resistant persons; a second group would contain able-bodied persons who are unemployable because of an atypical hereditary trait or a chromosomal anomaly that places them in a category of statistically higher risk of occupational illness. Moreover, because of the hereditary nature of genetic defects, future generations of the same families would be considered unsuited for work as well.

To develop a reasoned approach to the topic of employment rights of individuals with a proven high risk of illness, several questions need to be addressed. First, Who is at risk? Is it only the particular applicant or employee, or would coworkers or the public be endangered if there was a sudden onset of illness to the particular employee? Second, What is the nature of the risk? Obviously, different answers might be given if the risk was of dermatitis rather than cancer.

Third, What is the degree of risk? For example, if on the average 1 out of 10,000 agricultural workers developed skin cancer and 10 out of 10,000 agricultural workers with red hair and freckles developed skin cancer, the red-haired, freckled worker could be considered hypersusceptible but still would not be likely to get skin cancer.

Fourth, Who decides whether to accept the risk and on the basis of what information? What effect does an employee's risk acceptance have on possible workers' compensation claims or civil liability? Fifth, What are the employer's rights to be able to use employee selection methods it deems appropriate and to avoid additional cost?

These and other questions need to be addressed in order to formulate a well-reasoned public policy that will be responsive to these problems. In formulating this public policy, I would respectfully recommend that the subcommittee give some reference to OSHA, title 7, and the Rehabilitation Act, which have already expressed the following generally applicable public policies: First, to assure as far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources. Second, individuals are not to be discriminated against on the basis of immutable characteristics. Third, employment practices based upon stereotypes or presumptions are illegal; there must be an individualized determination of present ability to perform the job. Fourth, even accurate class-based statistics cannot justify individual discrimination. Fifth, employee selection criteria must be job related. Sixth, in appropriate circumstances reasonable accommodation and affirmative action may be required; and, seventh, some additional costs to the employer may be a necessary price to pay for maintaining equal employment opportunities. These are some of the policies which Congress has already effectuated through existing legislation as interpreted by the courts and through the statutory language itself.

Mr. Chairman, genetic and cytogenetic screening is a field in which the law has lagged well behind scientific developments. There is a strong potential that new scientific discoveries could be made in this field with a rapidity that would bring a variety of societal problems in their wake, and with which we are not presently prepared to deal.

This is not to say that research in this field should be discouraged or halted. On the contrary, genetic and cytogenetic techniques could be quite beneficial in identifying individuals in need of increased protection in the workplace and in the early detection of occupational disease. The danger is that these techniques will be used prematurely, indiscriminately, and with harsh consequences for higher risk categories of workers.

I would like to end with a quote from the book "Genetic Prophesy," by Harsanyi:

> Soon we may find ourselves caught in an ever-tightening spiral, finding markers for more subtle problems, discovering larger numbers of susceptible workers, labeling more and different types of environments as hazardous. It is not inconceivable that through screening, industry will become the modern counterpart of Diogenes as it searches for a perfect worker.

Thank you, Mr. Chairman.

[The prepared statement of Mark Rothstein follows:]

United States House of Representatives
Committee on Science and Technology
Subcommittee on Investigations and Oversight

Tuesday, June 22, 1982

# Some Legal Aspects of Biochemical Genetic and Cytogenetic Screening In the Workplace

Statement of

Mark. A. Rothstein
Professor of Law
West Virginia University

## I. Practical Differences Between Biochemical Genetic and Cytogenetic Screening

Before discussing some of the legal issues raised by biochemical genetic and cytogenetic screening, it is important to note some basic differences between the two procedures.

Biochemical genetic screening attempts to identify individuals with an *inherited* trait that may predispose the individual to occupational illness. Examples of these traits are glucose-6-phosphate dehydrogenase deficiency, sickle cell trait, serum alpha$_1$ antitrypsin deficiency, and thalassemia trait. When individuals with certain hereditary traits are exposed to certain workplace conditions, they are at a heightened risk of illness.

There are actually two types of cytogenetic testing. Classical clinical cytogenetics attempts to detect heritable chromosomal abnormalities in somatic cells. Occupational cytogenetics attempts to detect an increase in chromosomal damage caused by exposure to clastogenic substances. Because there appear to be correlations between chromosomal abnormalities and the development of cancer and other diseases, cytogenetic screening attempts to identify the cellular precursors of occupational disease.

The first difference between biochemical genetic and occupational cytogenetic screening, therefore, is that the former focuses on hereditary traits whereas the latter attempts to detect chromosomal changes caused by exposure in the workplace.

A second major difference between the two types of screening procedures is their predictive values. In general, the testing methods used to identify biochemical genetic traits have a higher predictive value than the cytogenetic techniques. Moreover, there are greater correlations between the trait and higher risk of disease than there are between induced chromosomal abnormalities and higher risk of disease.

A third difference is the extent of their current use by employers. Although there is little data and employers are quite reluctant to divulge the use of biochemical genetic screening, it is widely believed that many employers presently use one or more of these methods. Moreover, there is a substantial body of scientific literature advocating widespread use. Occupational cytogenetic screening, by contrast, is still largely an experimental technique. Reliable procedures have been developed only for a limited number of toxic substances and most experts do not advocate cytogenetic screening in industry at this time. These test methods are also much more expensive than the simpler biochemical test procedures.

Finally, a difference between the two types of screening procedures with major legal ramifications is that biochemical genetic screening often has a disparate impact along racial or ethnic lines. Cytogenetic screening has not yet been shown to have this effect.

## II. Common Law and Collective Bargaining

A number of legal issues are raised by biochemical and cytogenetic screening in the workplace. Unfortunately, there are few definitive answers. This is because many of these screening procedures are relatively new and because laws relating to the more traditional aspects of the employment relationship do not appear to cover biochemical and cytogenetic screening.

At common law, employers had virtually unfettered control in selecting their employees. The employer could hire or refuse to hire any person for any reason or no reason at all, including the employer's opinion about the medical fitness of the applicant or employee. To a large extent, this is still the current state of the law.

Although there is no legal duty to conduct preemployment or periodic medical examinations (except pursuant to certain OSHA standards), approximately 47.7% of all employees are required to take a preplacement physical examination and 33.7% of all employees are given periodic medical examinations. There is little or no regulation over what tests may be performed or what personnel action may be taken as a result of the tests.

Collective bargaining agreements often address company medical practices but do not usually address preemployment examinations or the employer's hiring process. Also, most collective bargaining agreements do not focus on specific medical procedures or tests, but only set out when the tests are performed, who pays for them, etc. Finally, it must be remembered that only about 20% of private sector workers are unionized.

## III. Federal Statutory Regulation

Three federal statutes, the Occupational Safety and Health Act (OSHA), the Rehabilitation Act, and Title VII of the Civil Rights Act of 1964, have a bearing on employer medical screening. None of these laws, however, address the problem directly and completely.

OSHA was enacted to mandate the elimination of safety and health hazards from the workplace. This is to be accomplished by enforcement of specific standards and the Act's general duty clause. Some of the specific OSHA health standards use medical surveillance of employees as a means of preventing occupational illness. In the usual case, the standards may detail what medical procedures must be performed, but they do not indicate what procedures may not be performed, nor do they proscribe any personnel actions that may be taken as the result of a medical determination. If the Secretary of Labor were to promulgate standards that protected the employment rights or job security of employees, it is quite likely that the standards would be struck down by the courts as being outside of OSHA's statutory authority.

The Rehabilitation Act of 1973 contains two sections prohibiting employment discrimination against the handicapped. Section 503 applies to persons with federal contracts in excess of $2500 and section 504 applies to recipients of federal financial assistance. "Handicapped individual" is defined very broadly to include "any person who (A) has a physical or mental impairment which substantially limits one or more of such person's major life activities, (B) has a record of such an impairment, or (C) is regarded as having such an impairment." There are several unresolved issues that would probably impede an attempt to use the Rehabilitation Act to remedy alleged discrimination through the use of genetic screening. First, it is not clear whether a heightened susceptibility to occupational illness is a handicap and therefore it is not clear whether the statute applies. Second, it must be established that a person with present ability, but a future risk of illness is "otherwise qualified." Third, it is not clear when an employer would be justified in using the screening procedures in employment decisionmaking. Finally, the extent of available remedies under the law has yet to be determined.

Title VII of the Civil Rights Act of 1964 prohibits all forms of discrimination in employment based on race, color, religion, sex, and national origin. Because certain biochemical genetic tests have a marked impact along racial lines (e.g. sickle cell trait), any differentiation based on such a test would establish a prima facie case of discrimination. It is possible, however, that an employer's business necessity or job-relatedness defense would justify such a practice. Nevertheless, at the present time, Title VII affords the best protection for a limited group of applicants and employees who can show discriminatory impact on a statutorily protected class.

## IV. State Statutory Regulation

The lack of adequate federal protection for employees exposed to hazardous working conditions has caused several states to enact a variety of protective laws. In New Jersey, a 1981 amendment to the state employment discrimination law specifically prohibits employment discrimination based on an individual's "atypical hereditary cellular or blood trait." This is defined to include sickle cell trait, hemoglobin C trait, thalessemia trait, tay-sachs trait, or cystic fibrosis trait. Thus, New Jersey has become the first jurisdiction to expressly proscribe the use of multiple forms of biochemical screening. Florida and North Carolina prohibit discrimination in employment based on sickle cell trait. In Maryland, an employer is prohibited from asking applicants about matters not directly related to the job, but permits a medical evaluation to determine the applicant's ability to perform the job.

A number of other recent state statutes dealing with related subjects demonstrate the increasing state involvement in occupational safety and health matters. Ten states (Cal., Conn., Mass., Me., Mich., N.Y., Or., Wash., W.V., Wis.) have "worker right to know" laws which require that employers notify employees of all the toxic substances in their workplace. Five states (Conn., Mass., Me., Ohio, Wis.) give workers the right to see their medical records. In Massachusetts, when the employer requires an employee to take a medical examination, the employee must be furnished with a copy of the medical report. California prohibits the disclosure of employee medical records without the consent of the individual. Connecticut requires that employers notify employees when they are working with reproductive hazards and make alternative work available when pregnant women are exposed to reproductive hazards.

It is quite likely that state initiatives will continue unless new federal legislation is enacted.

V. Conclusion

Current federal and state laws are inadequate in their treatment of biochemical genetic and cytogenetic testing in the workplace. It is foreseeable that new scientific advances will lead to the increased use of these screening procedures. Without sufficient controls, however, there is a real threat that individuals may be denied employment opportunities unfairly and whole classes of able-bodied individuals will be rendered unemployable. On the other ahnd, with proper use, these medical techniques could be of immense value in the early prevention and detection of occupational illness.

Mr. GORE. Thank you very much. That was really thoughtful testimony and most helpful.

Mr. English, we prevailed upon you to appear here at the very last minute and we appreciate your willingness to come on that basis. As a result, we have waived the requirement for a prepared statement but I would like to invite you to make any introductory remarks if you wish to do so.

## STATEMENT OF JAMES ENGLISH, ESQ., UNITED STEELWORKERS OF AMERICA

Mr. ENGLISH. Thank you very much, Mr. Gore, and we do appreciate very much the opportunity to be here.

I am the associate general counsel of the United Steelworkers of America and I am also cochairman of the American Bar Association's Committee on Occupational Safety and Health Laws. I do not speak here in that latter capacity; the ABA does not have a position on this, so far as I know. We think it is extremely important this this committee focus on the issue of genetic screening. We have a genuine concern that the rapid development of knowledge in this area may lead to the misuse of the information, particularly by excluding from workplace and from jobs persons who are otherwise qualified to perform work.

We, like you, were surprised at the early results from the study by OTA. We were particularly surprised at the 16 percent figure but I personally am even more surprised that 16 percent of the companies surveyed would be so candid as to indicate that they are thinking seriously of getting involved in genetic screening. I think we have to take that indication fairly seriously and obviously to the extent that there may be some reluctance on the part of other companies to respond at all, one might suggest that the percentage would be even higher had those other companies responded. That is, of course, speculation but it is at least speculation which appears to have some basis in experience.

The one other concern that I have about the study is that the identity of the companies responding is not known. Anonymity was provided. I understand fully the reasons why the study was constructed in that way. I think it is unfortunate, nevertheless, that that does offer a significant hindrance because to some extent the knowledge of what companies are doing it, why they are doing it, and the extent to which they are doing it may be of some significance.

Mr. **Gore**. You said a moment ago you were surprised they would indicate that they were. They might not have gotten a response, a useful, representative response if they had not gone about it that way.

They consulted with us about that decision. Obviously it was an important decision. We feel the issues are what are most important at this stage of the game and I concurred in their decision to go that route simply because I thought they were correct in assuming that the response would be not very good if they did not go that route.

Mr. **English**. I cannot quarrel with that concern. I guess what I am indicating is just an unhappiness that that appears to be a fact of life.

Mr. **Gore**. Yes.

Mr. **English**. Some years ago——

Mr. **Gore**. Incidentally, I think 7 of the 11 labor unions failed to respond. I believe that is correct.

Mr. **English**. I believe it was, yes, 7 out of 11, and I do not know what the reason for that is. I do not believe it would have been a reluctance to do so. I think it may have been a lack of knowledge but that, once again, is also speculation on my part.

Mr. **Gore**. Yes. Well, go ahead.

Mr. **English**. Genetic screening, by its very nature, is the kind of testing that if you are not doing it, you are not likely to know that it is being done because if you take a sample of blood, obviously it can be analyzed for different purposes.

Shortly after title 7 of the Civil Rights Act was passed, William Lloyd, an epidemiologist at the University of Pittsburgh, was in the midst of a study of the mortality of coke oven workers in Allegheny County in Pennsylvania. The early results of that study indicated that there was a statistically significant increased risk of death from lung cancer among coke oven workers.

When that data was broken down, it appeared initially that that statistically significant increased risk was among black workers and that if one looked only at white workers, one would not find that statistically significant increased risk. To the credit of the steel companies, no attempt was made or no thought was given, apparently, to a solution to that problem which I think we would all, then and now, have viewed to have been horrendous. No one suggested that the problem could be solved by removing black workers from coke ovens. In fact, in the years that followed as the data grew from that study it became clear that the problem of death from cancer among coke oven workers was not one that was limited on the basis of race, and that the early results showing that whites were not at a statistically increased risk were simply explainable on the basis that there were not enough whites in the sample to make that determination.

I would suggest that that particular situation offers an object lesson for this particular area. It seems to me that everyone agrees that while knowledge in the genetic screening area is growing, it is also quite clear that we do not know what we do not know, and we do not necessarily know the consequences of what we do know. For companies at this stage in the game to develop policies of exclusion because an individual is unfortunate enough to have the G6PD trait or the alpha-1-antitrypsin trait or whatever it happens to be is a very, very dangerous policy to embark on at this time, dangerous from a policy point of view and perhaps also dangerous from a legal point of view because I think that while cases have not yet been decided in this area, arguments can be made at least with respect to title 7 that there may be violations with respect to exclusionary policies which are over broad because they will be excluding more than simply those who will suffer from exposure in the workplace, and which at the same time adversely affect limited groups of individuals who are primarily falling within a particular race, sex, or national origin category.

In our judgment, genetic screening is an extremely valuable tool to be used in a lot of areas. In particular, determining who are susceptible workers may be valuable in terms of determining not who should be excluded but rather what substances in the workplace we should be looking more closely at. As Dr. Miller suggested this morning, and as I think others would agree, susceptible workers or persons who are more susceptible than others may very well be persons who are providing all of us with early warning and with knowledge. If we remove the workers immediately because we figure that some of those persons may be harmed, we may also be removing that early warning system.

I think these are other factors that should be considered in any kind of a policy which might be adopted by Congress, and as I indicated, I think that the issue of whether title 7 covers many of these areas is one which is yet to be resolved.

Thank you very much.

Mr. **Gore**. Well, thank you. All three of your statements I find extremely interesting.

All of you would agree that the information in the OTA survey, especially where it indicates that 54 organizations intend to use biochemical testing and 52 organizations intend to use cytogenetic screening, indicates that this testing is likely to become the source of serious legal concerns rather soon. Would all of you agree with that prediction?

Mr. **English**. Yes.

Mr. **Barnard**. It is possible to become, sir.

Mr. **Gore**. All right. This is a panel of lawyers, after all.

One of the more obvious issues is discrimination. All of you mentioned it. Since the issue is yet to be fully fleshed out, do you think it is likely that individuals judged to have genetic hypersusceptibilities would be protected from discrimination under the Rehabilitation Act? Mr. Barnard?

Mr. **Barnard**. Mr. Chairman, I would prefer that Professor Rothstein answer that. I have focused my attention on the OSH Act and title 7, and I will answer it with reference to title 7 but on the Rehabilitation Act I would prefer to have him respond.

If a test is being used——

Mr. **Gore**. Well, before you get to—you are going to go to title 7 and OSHA?

Mr. **Barnard**. Yes.

Mr. **Gore**. Let me ask you to hold on for a moment on that——

Mr. **Barnard**. Fine.

Mr. **Gore**. And I will ask Professor Rothstein to respond to the question. However, before doing so, is your decision not to mention the Rehabilitation Act in your testimony or analysis a reflection of any view on your part that it is not relevant to these issues?

Mr. **Barnard**. Not at all. It is just that in my practice and in the study that I have given to this, I have focused on the OSH Act and title 7, and I therefore feel that I can comment but I would prefer not to guess on other areas.

Mr. **Gore**. Fine, fine. Very good.

Professor Rothstein?

Mr. **Rothstein**. Well, my personal view is that the Rehabilitation Act would apply in these situations but the problem with the Rehabilitation Act is that, first of all, it does not apply to all employers. There are two sections that apply in this situation: Section 503 of the Rehabilitation Act prohibits discrimination in employment by individuals holding Federal contracts in excess of $2,500, and section 504 of the Rehabilitation Act is limited to recipients of Federal financial assistance, which would include State and local governments and any sort of private companies that received Federal money, so it has a limited coverage.

The second problem with the Rehabilitation Act is, even if it did apply, there is a problem of remedies. The courts that have heard these cases under section 503—not particularly genetic cases but cases generally—have held that there is no private right of action on behalf of employees to sue their employer. The only remedy is by filing a complaint with the Labor Department. That is under section 503, and under section 504 it is not clear to what extent the remedies would apply either. Therefore, even though they may theoretically be covered by the statute, as a practical matter, it is not likely to afford very much relief.

I should mention that there are approximately 41 States that have State rehabilitation acts on the books, and about half of the States to consider the issue have held that hypersusceptibility constitutes a handicap. Therefore, the answer is hardly clear and even if they are in theory covered, there is a definite problem because of a lack of remedies.

Mr. **Gore**. At our request the General Accounting Office has prepared a rather lengthy legal analysis of the relationship between genetic deficiencies or genetic hypersusceptibility to the Rehabilitation Act, and without objection I would like to put that into the record at this point. It is entitled "Statement of Facts Regarding Protection of the Handicapped From Employment Discrimination."

They generally agree with what you have just said, Professor. They went on to say that apparently the issue has never been tested through administrative or judicial proceedings, and also there are the problems with who can file suit, who can get into the court.

[Material to be supplied follows:]

## STATEMENT OF FACTS REGARDING PROTECTION OF THE HANDICAPPED FROM EMPLOYMENT DISCRIMINATION

Several aspects of current laws protecting handicapped persons from employment discrimination were reviewed. The primary objective was to identify limitations to the protection provided by title V of the Rehabilitation Act of 1973, as amended (29 U.S.C. 31 et. seq.). To do this an attempt was made to determine the number of employers excluded from the act and, through interviews with representatives of handicapped and civil rights organizations as well as private attorneys, to determine whether there are any significant limitations to the act's coverage and protection which are of concern to the handicapped. One specific issue addressed with regard to scope of coverage was whether persons with genetic deficiencies 1/ are protected under the act's definition of "handicapped persons." A second objective was to determine what protection State laws provide when the act does not apply.

Review work was limited to title V of the act because it contains the major Federal provisions related to employment of handicapped persons. Most of the review efforts focused on sections 503 and 504 of that title because they are most relevant to employment of handicapped persons by non-federal employers and because most of the individuals interviewed raised concerns about those sections.

A major part of the work consisted of interviews with attorneys and officials of various organizations representing the handicapped

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1/Genetic deficiencies are, essentially, genetically transmitted biological variations. They sometimes have little or no effect on those who possess them but can also result in disease. Three genetic deficiencies mentioned in this paper are sickle cell anemia, sickle cell trait, and hemoglobin C trait, all of which are genetically transmitted blood disorders.

(see attachment I), private attorneys who provide assistance to handicapped persons, and representatives of the American Civil Liberties Union and the National Association for the Advancement of Colored People's, Legal Defense and Educational Fund, Inc. These persons were interviewed to obtain their opinions concerning the adequacy of the act's coverage and the extent of protection it provides. They were asked to provide information concerning complaints filed in which employment discrimination was alleged on the basis of a genetic deficiency.

Also

--officials of Federal agencies with responsibilities related to preventing or investigating employment discrimination against the handicapped (including offlcals from the Department of Labor's Office of Federal Contract Compliance Programs (OFCCP), the Department of Justice, the Equal Employment Opportunity Commission, the Department of Education's Office for Civil Rights, and the U. S. Civil Rights Commission) were interviewed;

--the act, its legislative history, and implementing regulations were reviewed; and

--various legal references were reviewed to identify any cases or complaints which included allegations of employment discrimination based on genetic deficiencies.

Several reference sources 1/ were reviewed and, in some cases State officials were contacted, to determine what protection against employment discrimination State laws provide to the handicapped.

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1/The Law and Disabled People, Selected State and Federal Laws Affecting Employment and Certain Rights of People With Disabilities; President's Committee on Employment of the Handicapped; 1980; U.S. Government Printing Office, Washington, D.C.

Fair Employment Practices Manual, State Fair Employment Practices Laws, Bureau of National Affairs Labor Relations Reporter 8A; Bureau of National Affairs, Inc., Washington, D.C.

Fair Employment Practices Summary of Latest Developments, Bureau of National Affairs, State EEO Legislative Roundup - 1981; January 28, 1982; No. 438; Bureau of National Affairs, Inc., Washington, D.C.

Protections that State laws provide were also discussed with attorneys and organization officials.

## TITLE V

Title V of the act establishes Federal policy with regard to nondiscrimination against the handicapped. Sections 503 and 504 apply directly to employment of the handicapped by non-federal employers, and the review focused on these sections. Other sections, not reviewed, include, among other things, a requirement for Federal departments and agencies to take affirmative action toward employing the handicapped (sec. 501), establishment of the Architectural and Transportation Barriers Compliance Board (sec. 502), and a requirement that attorney's fees be paid to the prevailing party in any action or proceeding to enforce or charge a violation of title V (sec. 505). Section 505 also makes the legal remedies, rights and procedures established in title VI of the Civil Rights Act of 1964, (42 U.S.C. 2000d). applicable to persons filing complaints under sections 501 and 504.

The act defines a handicapped person as any person who (1) has a physical or mental impairment which substantially limits one or more of such person's major life activities, (2) has a record of such impairment, or (3) is regarded as having such an impairment. The act protects "qualified" handicapped persons, that is, persons who are capable of performing a particular job, with reasonable accomodation to their handicap. In order to be protected by the act the person must be capable of meeting the objective standards of the job. 1/

Section 503 of the act requires Federal contractors to take affirmative action in the hiring and advancement of handicapped individuals.

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1/The act specifically excludes current drug and alcohol abusers under certain circumstances.

The section applies to all contractors with contracts or subcontracts in excess of $2,500 for the procurement of services (including construction) and personal property. Section 504 of the act prohibits discrimination against otherwise qualified handicapped persons under any program or activity receiving Federal financial assistance. 1/ The section applies to both public and private financial assistance recipients, such as schools, hospitals, vocational rehabilitation agencies and State agencies, as well as to a variety of types of assistance, such as grants, loans, services of Federal personnel and real or personal property.

OFCCP administers section 503; section 504 is administered by the department or agency which administers the covered financial assistance program. These agencies' responsibilities include promulgating regulations, conducting reviews to assure the employers' compliance with the regulations and investigating complaints of discrimination filed under these sections. The Department of Justice's Civil Rights Division is responsible for coordinating activities under section 504 and has issued guidelines for the agencies to follow.

Job applicants or employees who believe they have been discriminated against because of a handicap or perceived handicap, may file a written complaint with the administering agency, i.e., OFCCP under section 503 or the applicable department or agency under section 504. Agencies are required to investigate the complaint promptly. If the investigation shows no violation of the act, the complainant will be notified. In these cases the complainant can ask for a review of the case by the Department of Labor under section 503 or the administering agency under section 504, as appropriate.

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1/In 1978 the Congress amended this section by extending coverage to "any executive agency" and the United States Postal Service.

If the investigation finds that the employer discriminated, the agency attempts to secure the employer's voluntary compliance through concilation and persuasion. If compliance is not attained the agency may institute formal enforcement proceedings, which must include a hearing if the employer requests one. Various penalties can be imposed under these sections, including termination of the employer's contract or financial assistance.

## UNKNOWN NUMBER OF EXCLUDED EMPLOYERS

The number of employers specifically excluded from coverage under sections 503 and 504 could not be determined. Section 503 excludes contractors with contracts of $2,500 or less and all noncontractors. OFCCP did not have information concerning the number of employers in these excluded groups. Absent information concerning the number of employers excluded, one indicator of the extent to which the act does not provide protection is the number of complaints received which cannot be processed because the act does not provide jurisdiction over the employer. OFCCP could not readily provide the number of complaints it had received in which the employer did not have a Federal contract, or did not have a contract in excess of $2,500. Although OFCCP headquarters could not provide the number of these "no jurisdiction" complaints, officials contacted in several OFCCP regional offices confirmed that these complaints were received.

Section 504 excludes employers who do not receive Federal financial assistance and employers receiving certain types of Federal monies, such as payments under insurance or guaranty contracts. The

Department of Justice has not yet responded to a request for information concerning the number of employers not covered by, and the number of "no jurisdiction" complaints filed under, section 504.

## PERSONS WITH GENETIC DEFICIENCIES

One Department of Justice official said that persons with genetic deficiencies are protected by the act, however, the issue apparently has not been tested through administrative or judicial proceedings. An official in Justice's Civil Rights Division said that a person with a genetic deficiency would be protected by the act if, because of that deficiency, the employer regards the individual as being handicapped. However, none of the attorneys, organization officials or government officials interviewed knew of any complaints alleging employment discrimination on the basis of a genetic deficiency which had been filed with administering agencies or with the courts.

Two employment discrimination cases were found involving a genetic deficiency--sickle cell anemia. However, both cases used the race discrimination provisions of title VII of the Civil Rights Act of 1964 as the legal basis for the complaint. Several attorneys interviewed told us that, if a handicapped complainant in an employment discrimination case were a female or a member of a minority group, they would, if possible, file suit under title VII rather than the Rehabilitation Act. They said they would use title VII because legal precedent has already been established under that title.

## COMPLAINANTS' PRIVATE RIGHT OF ACTION

Many of the attorneys and organization officials interviewed said that one of the most significant limitations to the protection provided by title V of the act is that under sections 503 and 504, respectively, complainants have no, or limited, right to bring suit against an employer. Many of those interviewed suggested that this deprives complainants of legal recourse to resolve their complaints. This right to individually file suit is known as private right of action.

Section 503 specifically provides for an administrative remedy through the Department of Labor. Individuals interviewed told us that most litigation involving this section has focused on whether a person claiming discrimination also has a private right of action. Four U. S. Courts of Appeals have decided that the Congress did not intend to create such a right under section 503.

One official said that this deprives complainants of legal recourse because, for example, if OFCCP finds "no discrimination" as a result of a complaint investigation, the complainant would not have the right to appeal OFCCP's decision to the courts. Another official said that lack of private right of action under section 503 is more significant in light of the backlog 1/ of complaints at OFCCP and the fact that complainants may wait several years until OFCCP completes its investigation.

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1/OFCCP officials have acknowledged that a backlog of complaints exists. They have also stated that they are working to reduce the number of complaints in the backlog.

Attorneys and organization officials interviewed were also concerned about limitations to complainants' private right of action under section 504. Five appeals courts have decided that an individual does not have a private right of action under this section with respect to employment discrimination except when a primary objective of the federal financial assistance is to provide employment, or when employment discrimination results in discrimination against the intended beneficiaries of the federal aid.

Some attorneys interviewed said that many individuals who would like to file employment discrimination suits cannot do so under section 504 because of these court decisions. Further, an official of the Department of Education's Office for Civil Rights said that because of these decisions, in States covered by the appeals courts' rulings, the agency is barred from investigating complaints which do not fall within the courts' exceptions.

## STATES PROVIDE VARYING PROTECTION

Because the act does not cover all employers or handicapped persons, nondiscrimination in employment statutes in the 50 States, Puerto Rico, and the District of Columbia were reviewed to identify the protections available to handicapped persons when sections 503 and 504 of the act do not apply. Although most of them have enacted statutes protecting handicapped persons against employment discrimination, in many cases there are limitations to their scope of coverage or protection. There are significant variations in these laws, such as in definition of handicap, the types of employers covered, and the existence of enforcement agencies.

Forty-seven States and the District of Columbia have enacted nondiscrimination in employment statutes which include handicapped persons among the protected groups. South Carolina, North Dakota, Puerto Rico, and Wyoming have no such statutes. All of the 48 statutes cover, with varying definitions, physically handicapped persons, but only 25 cover mentally handicapped persons.

Only three State statutes specifically include a reference to genetic deficiencies. Statutes in North Carolina, New Jersey, and Florida prohibit discrimination in employment against individuals with sickle cell trait. The North Carolina and New Jersey statutes also specifically prohibit discrimination against persons with hemoglobin C trait. In addition, Florida's statute prohibits public employers and organizations from conducting mandatory screening for sickle cell trait as a condition for employment.

To determine whether complaints of employment discrimination based on these two deficiencies existed before these provisions were enacted, or in part resulted in the provisions' enactment, officials were contacted in the three States to obtain information concerning the provisions' legislative histories. However, they could not provide such information. They said that no complaints or suits involving genetic deficiencies had been filed under their respective statutes.

There are significant differences in the types of employers covered by the 48 statutes. For example, 42 statutes include government agencies, 25 include employers supported wholly or in part by public funds or public works, 43 include private employers, 37 include labor organizations, and 36 include employment agencies. The total scope of the coverage also varies significantly. For example, 17 statutes include all of the above types of employers, while others include only one or two.

There are also differences in the enforcement mechanisms provided by the statutes. Of the 48 statutes prohibiting employment discrimination against the handicapped, 38 establish enforcement agencies which usually investigate and resolve complaints alleging discrimination against the handicapped. Ten do not provide for such agencies, and complainants, if they are covered by the law, must resolve their complaints through the judicial process by bringing suit against the employer.

## ORGANIZATIONS CONTACTED

American Civil Liberties Union
New York, New York

American Coalition of Citizens
with Disabilities
Washington, D.C.

American Council for the Blind
Washington, D.C.

American Foundation of the Blind
Washington, D.C.

Blinded Veterans Association
Washington, D.C.

Disabled American Veterans
Washington, D.C.

Disabilities Law Center
Boston, Massachusetts

Governor's Committee on the Handicapped
Montgomery, Alabama

Governor's Committee on the Handicappped
Annapolis, Maryland

Governor's Committee on Employment of
the Handicapped
Cheyenne, Wyoming

Governor's Council on Human Resources
Bismark, North Dakota

Howard University
Equal Employment Opportunity Clinic
Washington, D.C.

Legal Action Center
New York, New York

Legal Services Corporation
Montgomery, Alabama

Mainstream, Inc.
Washington, D.C.

Mental Health and Developmental
Disability Law Project
Chicago, Illinois

Mental Health Review
Washington, D.C.

NAACP Legal Defense and
Educational Fund, Inc.
New York, New York

National Center for Law
and the Deaf
Washington, D.C.

Rehabilitation Services Client
Assistance Programs
Montgomery, Alabama

Mr. **Gore**. Mr. English, did you want to say something about this, the Rehabilitation Act?

Mr. **English**. I would only make one comment, and that is, whether an individual has a particular trait may or may not be construed to be a disability. The existence of a trait may simply put that individual within a category of persons, which category has been statistically demonstrated to be susceptible. The individual himself or herself may or may not be susceptible, so I would think that the issue will be one that we could have quite spirited litigation about.

Mr. **Gore**. Yes. Now, Mr. Barnard, would title 7 of the Civil Rights Act completely protect individuals whose genetic susceptibility is limited to certain races?

Mr. **Barnard**. Title 7 forbids disparate treatment on the ground of race, provided the purpose of the treatment or the basis of the treatment is discriminatory. If the difference in treatment is related to a genuine, bona fide occupational qualification, and that includes avoidance of health risks that are unreasonable, and if the data are sound medically and scientifically, then the difference in treatment is not discriminatory. It is based on sound medical or scientific basis.

I think that to answer a question such as that, Mr. Chairman, generically or in general makes it extremely difficult to give you an accurate or a precise answer because it will depend on the facts in the particular case: how good the data base is, and whether the person who was making the differentiation was doing it on a reasonable and scientifically sound basis.

Mr. **Gore**. Well, that is interesting. Let me ask you a hypothetical, or let me construct a hypothetical and ask you a question about that: If one assumed a genetic susceptibility could be determined with accuracy, a high degree of accuracy, and that it gave evidence that the individual with that genetic susceptibility had a significantly higher risk of occupational disease or hazard, and if you stop the hypothetical at that point, your testimony is that if it is soundly based in science or medicine and if the test is scientifically sound, then that would be permissible?

Mr. **Barnard**. And if the qualification which the test measures is a genuine, bona fide occupational qualification that can be said to be job related. The way the courts have applied these tests, they have also insisted that the employer demonstrate some kind of reasonableness in the way in which he does it. In the case of the man who was asthmatic, the court was satisfied that the employer had tried to find places where the man could work, and ultimately concluded that in the particular employment atmosphere in which the man was being offered—was employed, that the employer could not reasonably protect the man's health. Under the circumstances, the court said that was a sound medical reason for dismissal because he could not reasonably protect his health.

Mr. **Gore**. Now let me change the hypothetical. Everything is the same except that it is now determined that the particular genetic marker is always associated with one race. Would title 7 prohibit the use of such a marker under those circumstances?

Mr. **Barnard**. Let me answer your hypothetical with a hypothetical: If you assume that an individual who has a genetic disability, such as the person who had xeroderma pigmentosa, and therefore cannot go outside during the daytime because they react very violently to ultraviolet rays, if you assume that that genetic trait is a race marker, as you have put it, then I think that the identification of a trait of that kind which makes that person so violently susceptible to ultraviolet rays, it would be gross abuse for an employer to hire that person as a farmworker to work in the fields. It would be absolutely outrageous to do that. If any employer who knew that a person had that susceptibility and exposed him to that kind of a risk, I would think that you would condemn that person on both sides of the street, up and down.

Now if the test is different—if the disease is, as Professor Rothstein said earlier, is a skin disease, some kind of dermatitis—that is a different problem. If the probabilities that you are talking about are a low probability that this will occur; if your data base is not very good; if the test itself does not have the kind of predictability you want, then a court might well conclude that if you rely on that, what you are doing is making a race discrimination, not making a sound medical judgment.

I think, Mr. Chairman, answering these things in sort of general terms becomes very difficult to be honest and to be fair.

Mr. GORE. Yes. Well, I appreciate that fact, and I am not trying to pretend that the questions are easy ones. I appreciate the fact that the answers are certainly necessarily difficult and complex but the answer is, stripped of the other stuff, the answer is that by itself title 7 would not in those circumstances automatically preclude a distinction that was otherwise permissible on the BFOQ analysis that was made earlier, if the harm to be avoided was above a particular threshold.

Mr. BARNARD. You have given a fairly complicated answer which I think is fairly straight.

Mr. GORE. OK. Now to address the issue of protecting a worker's health, would the general duty clause of the Occupational Safety and Health Act require a company to use genetic screening methods if such methods were found to be valid?

Mr. BARNARD. The general duty clause, as Congress passed the statute, has a rather narrow and precise area of application. The general duty clause does not apply in those cases where there is a standard in place that OSHA has adopted. It is designed to fill in gaps where there is no OSHA standard that is of a kind that is the common standard that we know about.

In order for the general duty clause to apply, the hazard or the danger must be one that is recognized by the employer or is generally recognized in industry itself, and there must be what the cases call a "feasible abatement method."

Now getting back to your hypothetical, if you assume that a highly predictable genetic test of some sort were devised and that what that test demonstrated was a characteristic which was an important characteristic, involved significant hazard or significant danger, and it was identified by a test that was generally recognized or that the employer himself recognized was the kind of test that should be used—yes, I could conceive of a situation in which general duty would become applicable and OSHA would have to show in its inspection that there was a feasible abatement method to take care of the hazard which was found by that reasonably recognized method.

Mr. GORE. Professor Rothstein?

Mr. ROTHSTEIN. I think it is theoretically possible but it is not very likely to take place, for some of the reasons that Mr. Barnard outlined and also because the general duty clause only can apply in situations where a hazard is recognized, that is, either by the employer or the industry. We are talking about rather threshold scientific issues here and for the foreseeable time these hazards are not likely to be recognized. Even if they were, I think OSHA has enforced the general duty clause to apply to rather singular occurrences. Where there is some development in the scientific field that suggests that many employees are subject to the same types of conditions, then I believe what Congress intended and what OSHA has done in those situations is to use its rulemaking authority. Therefore, I think the general duty clause is probably not going to afford much of an avenue for relief here.

Mr. GORE. Mr. English?

Mr. ENGLISH. It is interesting because I was talking on the airplane coming down with one of our industrial hygienists and he made me aware of a disease called Wilson's disease. As I understand it, Wilson's disease is the absence of a certain gene which makes everyone who has it extremely susceptible to copper or to exposure to copper, to the point where anyone with Wilson's disease would find it almost impossible to work in a copper smelter. I suppose one could construct, therefore, an argument that a company-operated copper smelter would have an obligation to provide some kind of a test to determine whether or not an individual had Wilson's disease.

I do not believe that the general duty clause would go that far as to require it, and I would bottom my position on the fact that the number of people who have Wilson's disease is so small that I do not believe the general duty clause was designed to operate in that kind of a fashion. I suppose it might be possible that you could think of a disease which was so common to such a large number of people in a working environment that the general duty clause might impose some kind of an obligation to test in advance of assigning to an area.

Mr. BARNARD. May I add a word, Mr. Chairman?

Mr. GORE. Surely.

Mr. BARNARD. My discussion of the general duty clause was in terms of the cases that have been decided and the way in which the general duty clause has been handled in enforcement proceedings. I would like to say just a word for the general duty clause. In it, Congress spoke of the duty of an employer to provide a safe workplace, and I believe that one of the reasons that we find the general duty clause so little applied is that employers have responded to either what Congress has said, what they feel internally, the threats of litigation, or whatever you want to believe—responded in the direction of providing safe workplaces. It is a rare employer who does not want to have a safe workplace. It is a rare employer who wants to deliberately expose his workers to a hazard if he can avoid it, and it seems to me therefore that while my initial statement may have suggested the general duty clause is unimportant, I do not want to have anyone come away with the feeling that employers feel that the general duty has no meaning to them or that they should not be providing a safe workplace. I think they believe they should.

Mr. **Gore**. Yes. Now obviously the degree of predictive value is an important issue. All of you have discussed that as well. Last fall, at the subcommittee's previous inquiry, the counsel for one of America's major railroads testified that as a liability consideration, if a medical screening test gave just a 5-percent greater prediction of susceptibility to injury, the company would be required to use the test. In this case the company was operating under a somewhat different legal standard because of the statute involved with the railroad industry. Are you all familiar with the Federal Employees Liability Act?

Mr. **Barnard**. In general terms.

Mr. **Gore**. Would you agree that a 5-percent increase would be considered a legal requirement under that act?

Mr. **Barnard**. May I give a complicated answer, Mr. Chairman?

Mr. **Gore**. Sure, sure, if I can follow up with——

Mr. **Barnard**. A complicated question?

Mr. **Gore**. Right. [Laughter.]

Mr. **Barnard**. Mr. Chairman, it depends on what aspect of the data and the test is being addressed. It depends on whether the subject matter which is being addressed represents a hazard of significance or a hazard that would be regarded as being relatively unimportant.

If the data are valid in the sense that you can make a prediction as to the probability of injury to an individual by reason of exposure to a particular condition, then it seems to me what you are dealing with is—what do you regard as the legal responsibility—or what do you regard as the responsibility, forget the word "legal"—of an individual who is an employer faced with having to deal with people in that category? Is it responsible for him to have 1 in every 20 employees come down with a terribly serious illness? Is it responsible for him to have 1 of every 20 employees suddenly become totally incapacitated?

It seems to me what you have to deal with is the nature of the hazard, the reasonableness of the data, the reasonableness or the validity of the underlying data that they are relying on, the likelihood of the injury, the nature of the injury, and what can be done in the way of avoidance. All of these have to be tested reasonably in order to answer a question. I can see how a hazard to 1 in 20 employees, if it was a serious hazard, could be regarded by somebody—by most people—as being a fairly significant hazard.

Mr. **Gore**. Now would you agree that a marginal predictive value would be of assistance to an employer in defending against the lawsuit by an employee who claimed that he was discriminated against as a result of a biochemical or a cytogenetic test?

Mr. **Barnard**. No. Happily, I think the courts have been quite willing to inquire as to the reasonableness of the basis on which an employer makes his decision. They have been willing to listen to the criticisms of the validity of the data base, they have been willing to listen to the criticisms of the predictability of the test, and if they conclude that a person acts reasonably in light of all of the facts available, then I think they can reach the conclusion that it was a reasonable type of action in light of all of the circumstances.

I do not think the courts—and I hope the lawyers—blind themselves to the fact that these issues involve consideration of quite a number of factors.

Mr. **Gore**. Which statutes are the most likely candidates for change if biochemical and cytogenetic testing methods become more prevalent? I would like to ask all of you to be brief in your answers to this question. In other words, if the progress in this area of science is as rapid as many believe it to be, and the validity, predictability, precision of these tests improves greatly in the next few years and they become much more commonplace, and the Congress decides that some irrational decisions are being made and people in the work force are, yes, receiving more protection but in some cases being discriminated against in an invidious way, and the Congress chose to remedy that problem, what statutes should first be examined as vehicles for change?

Mr. **Barnard**. Congressman, guessing how this will happen, what it will look like, is a real crystal ball operation. You have staged a situation in which you have a valid test, a valid criterion, and some kind of end point associated with that which is medical or scientifically identifiable as an end point. At that stage in the game, as things now stand I am not sure that the existing legal structure, with the possible exception of the Rehabilitation Act, is not by itself capable of dealing with the situation as it will arise. The Rehabilitation Act as interpreted by the Supreme Court—and I will defer again to Professor Rothstein—does not give an individual right of action. It provides for Federal action or State action but not an individual right of action.

It may be that there is need for an individual right of action but if you are talking about the area in which OSHA acts, the area in which title 7 is being enforced, it seems to me that Congress has laid a foundation in which a valid, predictable test, as you defined it, can be fitted and structured under the rules and regulations that the courts have now adopted.

Mr. **Gore**. Professor Rothstein?

Mr. **Rothstein**. In my view title 7 would be the best place to start with respect to employment discrimination but the problem goes beyond that because title 7 does not give the EEOC rulemaking authority. I think that rulemaking in this area might be necessary in order to determine which types of tests have some proven validity and what test scores are significant, so that some guidance can be given to personnel in medical departments.

Mr. **Gore**. Under OSHA?

Mr. **Rothstein**. Under OSHA. I would say that title 7 and OSHA would be needed to correct the problem.

Mr. **Gore**. Therefore, you think existing OSHA authority might allow the Government to handle much of the problem through regulation?

Mr. **Rothstein**. No; I do not. I think OSHA would have to be amended because——

Mr. **Gore**. You think it would have to be amended to give it additional authority.

Mr. **Rothstein**. Well, as I interpret the act and the cases, the act was passed to clean up workplace conditions themselves and not to protect employee rights generally——

Mr. **Gore**. Yes.

Mr. **Rothstein**. Therefore, employment rights would have to be protected under title 7 unless OSHA were amended somehow.

Mr. **Gore**. Well, we may have to consider some minimum standards on false negatives and false positives and predictability.

Mr. **Rothstein**. Well, in that sense I think NIOSH research and OSHA rulemaking would probably be the most appropriate.

Mr. **Gore**. Mr. English?

Mr. **English**. My own instinct is, the Rehabilitation Act would be the area in which legislation of this kind would most appropriately be fit, with the understanding that the kind of rulemaking that Professor Rothstein is talking about would be invaluable in terms of providing guidance to the parties.

Mr. **Gore**. OK, very good. Could we supply a few additional questions in writing? I do not anticipate very many. We have another matter on the floor. Could you all respond just briefly to a few additional questions?

Mr. **Barnard**. Certainly.

Mr. **English**. Sure.

Mr. **Gore**. All right. There will not be very many.

I really appreciate your help today. It is a difficult area but I am convinced that in this period of unprecedented change, if the Congress is going to adequately do its job it is going to have to spend a little bit more time anticipating issues before they are fully mature and upon us. This is clearly an area where we can anticipate some problems in the future, and you all have been very helpful in telling us what the most likely contours of the issue are going to be. Thank you very much for your help.

The hearing is adjourned.

[Whereupon, at 1:15 p.m., the subcommittee recessed, to reconvene at the call of the Chair.]

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